

National Institutes of Health (U.S.) Office
of the Director

DR. ROBERT Q. MARSTON'S

SPEECHES AND ARTICLES

Volume III

DR. ROBERT Q. MARSTON'S
SPEECHES AND ARTICLES

Vol. III

<u>DATE</u>	<u>PLACE</u>	<u>TITLE</u>	<u>See TAB</u>
4/29/72	Los Angeles, Calif.	Health manpower needs and opportunities. (Presented to the Student American Medical Assoc.)	<u>1</u>
5/8/72	Baltimore, Md.	The role of the Federal Government in support of research. (dedication of O'Neill Laboratories, Johns Hopkins University)	<u>2 & 3</u>
6/1/72	Airlie House	The role of the Federal Government in support of biomedical research. (International Endotoxin Conference)	<u>4</u>
6/4/72	Chicago, Ill.	A favorable outlook on optometry. (Presented at Illinois College of Optometry's Centennial Graduation Ceremony.)	<u>5</u>
6/8/72	Philadelphia, Pa.	Old truths in new wrappings. (Presented at 125th Commencement at Hahnemann Medical College.)	<u>6</u>
6/18/72	Wash., D.C.	No title. (Delivered before the IV International Congress on Endocrinology.)	<u>7</u>
7/25/72	Woods Hole, Mass.	Background information on the organization and budget of the National Institutes of Health. (Symposium on National Policy and the Life Sciences, Marine Biological Laboratory)	<u>8</u>
10/14/72	San Juan, Puerto Rico	Background information on the organization and budget of the National Institutes of Health. (annual mtg. of the Assoc. for Academic Health Centers)	<u>9</u>
10/27/72	N.Y.C.	Reflections on science and medicine. (Presented at the Academic Convocation, Mount Sinai School of Medicine.)	<u>10</u>

DR. MARSTON'S
SPEECHES AND ARTICLES--VOL. III (CONT.)
Page 2

<u>DATE</u>	<u>PLACE</u>	<u>TITLE</u>	<u>See TAB</u>
11/5/72	Miami Beach, Fla.	Background information on the organization and budget of the National Institutes of Health. (Presented to the Assoc. of Professors of Medicine at the annual mtg. of the Assoc. of <u>American Med. Colleges.</u>)	<u>11</u>
11/10/72	Charlottesville, Va.	Medical science, the clinical trial and society. (dedication ceremonies for the McLeod Nursing Building and the Jordan Medical Education Building at the University of Virginia)	<u>12</u>
4/27/73	NIH	Farewell address.	<u>13</u>
5/3/73	Birmingham, Ala.	The relation of science to medicine. (Guest Lecture at 10th Annual Medical Student Research Day, University of Alabama Medical School)	<u>14</u>

11686
HEALTH MANPOWER NEEDS AND OPPORTUNITIES

Robert Q. Marston, M.D.
Director
National Institutes of Health
Bethesda, Maryland

Last month about 300 students of several health professions and allied occupations attended a health manpower conference in Chicago. The conference was sponsored by eight student health organizations, including the Student American Medical Association, and funded by the Bureau of Health Manpower Education, a component of the National Institutes of Health. I have not yet seen the conference proceedings, which are being edited and compiled into a final report, but I understand that there were more than 30 recommendations on such matters as recruitment, minority problems, professional education, and interdisciplinary student projects.

The conference was another demonstration of the deep, constructive interest which you and your colleagues have shown in the total health care system as you prepare to enter it. The conference also was an example of the essential dialogue and sharing of concerns between the professionals who constitute the

To be presented to the Student American Medical Association,
Los Angeles, California, April 29, 1972.

present system with the professionals in training who will in time themselves be responsible for the delivery of health care.

The increased concern with manpower problems--is well justified. With more than $4\frac{1}{2}$ million employees, the health industry has become the Nation's largest employer. Our supply of health workers has doubled in just the past decade. As recently as 1950, most of today's physicians were not yet in practice. Yet the problem of access to medical care for vast numbers of our population does not seem to be greatly improved, if at all.

Since 1950, the number of physicians has risen by more than 100,000--to a total of about 334,000, yet we don't seem to have enough to go around. Nevertheless, the competition to get into the schools of the health professions is keener than ever, with thousands of qualified applicants being turned away.

It is only natural that people are beginning to ask why there is still a health manpower problem and why the gains we have made have not had a greater impact.

The causes of our health manpower problems, even though they may be familiar to you, are worth mentioning again, so you may judge how your own career plans can help improve the situation.

Much of the new physician manpower, of course, has gone simply to take care of the Nation's rapidly rising health workload. Demands for health manpower have been increasing steadily with the size of the Nation's population and increased consumer income. Other factors driving demands for health care upward have been the rising educational attainment of the public, expanded insurance coverage, and public commitments to extend health services through programs such as Medicare and Medicaid.

Trends within the medical profession itself have tended to aggravate the problem. A few decades ago the specialist was in a very definite minority, but by last year more than 75 percent of the Nation's physicians were actively engaged in one of the specialties. While this speaks highly for the quality of American medical care, a serious problem has developed in the availability of the general practitioner and other providers of primary family care. Further, too few new physicians set up practice in the geographic areas where the need is greatest. Physicians are not moving in sufficient numbers into the inner-city or into rural areas.

These problems of numbers, location, and specialty are further compounded by serious racial imbalances. The Nation's 23.5 million black citizens--11.5 percent of the population--are not only underserved in terms of health care, but are under-represented as professionals. They account for but 2 percent of the Nation's physicians, 2.7 percent of the dentists and 5.7 percent of the professional nurses. Clearly there is much to be done to improve the motivation to enter the health field, to ease the economic pressures, and in some cases improve the quality of minority education which too often handicaps the minority student in competing for admission to the Nation's medical schools.

More than 35,000 applicants are now being considered for the 12,970 places that will be available to the incoming class of medical students this fall. A significant number will be denied admission simply because there is no room for them. The unavoidable rejection of qualified applicants at a time when the demand for physicians is so great is a highly frustrating fact of life today. It penalizes the committed student who has chosen to help meet a recognized social need. Though qualified, he is thrown back into the occupational supermarket, perhaps to be lost to a health care

These problems are certainly not going to solve themselves, but they can be solved if we work at them--energetically and in a spirit of cooperation. The Comprehensive Health Manpower Training Act of 1971, enacted last November, gives us some of the tools.

To encourage the schools of the health professions--medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, and veterinary medicine--to expand their enrollments the new law includes a capitation grant program. Schools now receive funds on the basis of their enrollment and their assurance to expand by at least a given minimum. Bonuses are provided for schools which expand beyond the minimum levels. The Bureau of Health Manpower Education reports that a number of medical schools have already responded to this incentive. All medical schools have applied for the capitation grants, which require them to assure a minimum increase of enrollment. Sixty-four have indicated they will exceed the minimums in order to qualify for bonus funds.

The Act also supports the construction of health professions schools through grants, loan guarantees, and interest subsidies. Grants are also authorized to speed the opening of new medical schools.

Loan and scholarship assistance to the student has been increased, with maximums now raised to \$3,500 a year. Loan forgiveness provisions have been added for students who agree to practice in shortage areas.

Other new grant and contract programs have been established for:

- *Special projects to expand or improve training in the health professions,

- *Training teachers in the health professions,

- *Establishing training programs in hospitals for family medicine, and

- *Making Health Manpower Initiative Awards to finance health education for underserved areas.

This important legislation is just the latest chapter in the nine-year Federal effort to help solve the Nation's health manpower problem. The transfusion of more than \$1.4 billion over the past nine years into the schools of the health professions has helped invigorate them to the greatest spurt of growth, improvement, and innovation since the modern system of medical education was established some 60 years ago.

Our medical schools graduated 7,300 M.D.'s in 1963, and this year they will graduate about 9,000. Since 1965, 20 new medical schools have been established, more than in the previous three decades combined.

First-year black enrollment in medical schools has risen from 3 percent--only 265 students--in 1963 to 7 percent (897 students) in the current school year.

Within the schools the trend is toward shortened curricula, more electives, a reemphasis on family medicine, the integration of educational goals with the needs of the community, and the development of allied professions.

Around the Nation many medical schools have recently introduced new teaching programs. At least 30 medical schools have shortened the traditional four-year curriculum or plan to do so.

As you can see, it takes a variety of approaches, in the training field alone, to get at our manpower problems. And it takes time. Progress is slow--much slower than any of us would wish--but it is discernible.

But manpower education is only part of the answer. We must make better use of the people we have, we must give them the tools and resources they need, we must assure the availability of high quality medical care to all our citizens. We are committed to those goals. A number of measures have been proposed to revitalize the health care system, to close the gaps and inequities, to increase efficiency and encourage innovation. And we are expanding our research efforts, particularly in such fields as heart disease and cancer, to find answers to age-old but still elusive questions. Only through research can we gain the knowledge to prevent as well as to cure disease. Prevention is, of course, the best way to ease the pressures on our scarce manpower resources.

I urge you to become acquainted with the President's Health Initiatives, with the measures now being considered by the Congress, with the range of ideas under discussion by health leaders and concerned laymen throughout the country. Your views and ideas will be valuable to the ongoing national dialogue. And out of this dialogue a new consensus can emerge which can lead to better health for the American people.

467
President Nixon has asked that I bring his special greetings and congratulations to you. He requested that I express to you his interest in the development of the Thomas O'Neill Memorial Laboratories and his best wishes for their future. 1/

- 1/ To be presented at the Dedication of O'Neill Laboratories, Johns Hopkins University, Baltimore, Md., May 8, 1972.

THE ROLE OF THE FEDERAL GOVERNMENT
IN SUPPORT OF RESEARCH

By

Robert Q. Marston, M.D.

I am delighted to participate in these dedication ceremonies for the O'Neill Memorial Laboratories of the Johns Hopkins University and the Good Samaritan Hospital

The launching of a new facility to be given over to research in the cause of human health is reason enough for celebration. But in this case, there are several added dimensions that make the occasion even more noteworthy: your association with one of the Nation's leading universities and biomedical centers; your staff of outstanding scientists, already well known for their contributions to the development of new knowledge; your areas of concentration in the promising fields of immunology and transplantation; and your affiliation with a hospital which has special programs and expertise in these fields.

To be presented at the Dedication of O'Neill Laboratories,
Johns Hopkins University, Baltimore, Md., May 8, 1972

All of this makes the outlook for the future of your new laboratory bright indeed. All of us here are privileged to be present at this auspicious beginning.

I have yet another, personal reason for pleasure at being here today. You at this facility and we at the National Institutes of Health are not only near neighbors but active partners in a number of endeavors. It is a source of pride to us at NIH that we are able to support some of the work under way at these laboratories.

Recently, the NIH's National Institute of Allergy and Infectious Diseases developed a program to establish Allergic Disease Centers throughout the Nation, and Good Samaritan was one of the first institutions to be Awarded support for such a Center.

I have, in fact, often described the biomedical research enterprise in this country as a consortium of agencies and institutions working toward a common goal. This afternoon, I would like to examine the role of the Federal partner in this enterprise, drawing primarily for illustration on the mission and the work of the National Institutes of Health.

In the long run the state of health in this country and the individual citizen's prospects for a long and productive life depend on the initiative and imagination with which our scientists pursue the advancement of knowledge. Thus a basic

strategy of the Federal health effort is to emphasize those activities such as research which, in the long run, will fundamentally improve the health prospects of the Nation.

The history of medical research in this country is therefore in large measure a history of the involvement of the Federal Government in seeking the solution to national health problems. Until late in the 19th century, American medicine was dependent on the advances made by such pioneers as Pasteur, Koch, Lister and Ehrlich in the great European universities and medical schools.

Our government first became involved in medical research in a public health context when a "laboratory of hygiene" was established at the U.S. Marine Hospital on Staten Island, New York. The laboratory's primary concern was to deal with cholera and other infectious diseases arising from the increasing numbers of immigrants arriving in the Port of New York. Out of this very specialized function, the laboratory and its successor, the National Institute of Health--gradually developed an expanding national program of research on infecti

diseases during the late 19th and early 20th centuries.

It was not until the National Cancer Act of 1937 that a major effort was made to investigate the most complex of chronic diseases. This legislation created the National Cancer Institute, later incorporated into the National Institutes of Health, and helped establish the precedent for research through grants-in-aid to non-Federal scientists.

The enactment of the Public Health Service Act of 1944 gave the Surgeon General broad authorization to foster, conduct support and cooperate in research relating to health and disease. Authority to award funds for non-Federal research and research training, until then limited to cancer, was extended to health problems generally.

The success of research in solving major problems--including medical and health problems--connected with the national effort during World War II did much to encourage postwar public investments in science and technology. Research activities in all sectors of the Nation--academic, industrial, governmental--began to expand; research became more professionalized; and sponsorship patterns began to shift.

The rapid growth in Federal support for biomedical research is essentially a phenomenon of the past 25 years. In 1947 the total national investment in biomedical research and development was about \$87 million, and today it is roughly \$3.3 billion. There was a plateau in NIH funding from 1967 to 1970, but the downward drift was checked in 1971. In fact, the NIH budget for the research institutes and divisions has increased about 40 percent in two years to a total of almost \$1.5 billion in 1972.

Today the NIH accounts for almost 60 percent of all Federal support for biomedical research and development, and its role is larger than the figures indicate because most of its support is to nonprofit institutions, particularly universities, which currently receive some \$800 million each year.

NIH presently supports:

- . about 11,200 research grants in the amount of \$676 million
- . about 2,100 training grants for some \$131 million;
- . about 4,000 fellowships and career development awards at about \$25 million.

The rapid and significant growth of NIH, and of biomedical research in general, has been concurrent with a new concern for reordering priorities, growing consumerism, changing economic relationships internationally and domestically, continuation of the civil rights struggle, and a sense of the urgency of problems of the ghetto, of population, of pollution, and of possible exhaustion of vital resources.

It is inevitable then that biomedical science, now a very sizable enterprise, would be a topic of concern for non-scientists and indeed for the political process.

Another compelling reason for its public visibility is the increasingly urgent problem of the delivery of health services to the American people. Such societal pressures, expectations and hopes, predictably have had a significant impact on the ways in which the increased funds have been distributed. Thus, of the 40 percent increase I mentioned earlier--roughly \$400 million--\$200 million is invested in cancer, \$60 million in cardiovascular and \$30 million in population research, earmarked to a greater degree than in the past for expenditure through centrally programmed targeted efforts.

Equally significant as the increased targeting, has been the great effort by professional and lay groups to gain additional visibility for the area of their particular interest. You all know about the pressures in the fields of cancer and heart disease. Campaigns have also been mounted, and legislation introduced, to confer Institute status and to increase the amount of support in such areas as population, gerontology, gastroenterology, sickle cell disease, and kidney disease.

This kind of concentration of purpose and resources runs head on against a history of evidence that major innovations in medicine have emerged largely as the result of the work of individuals and small groups pursuing ideas arising out of their own experience and reflecting their personal creativity. Yet we have already taken significant steps toward a new way of doing business: the targeted program approach to research, reminiscent of some of the successful programs in technology and development. The advocates for these two positions have become in some ways more highly polarized than was the case a few years ago. Fortunately, increased support overall has

it possible to accommodate the emphasis on targeted research without serious disruption of investigator-initiated research.

As Director of NIH, I have supported both targeted programs and regular research projects on the grounds of what I believe to be sound philosophy. However, in recognition of the fact that undifferentiated research fares less well in non-scientific decision making than the highly visible targeted programs, I have swung my weight when possible toward the maintenance of investigator-initiated research projects, and I shall continue to do so in the future.

The research programs for which additional funds are requested in the 1973 NIH budget--cancer, arteriosclerosis, lung diseases, sickle cell anemia, and population research--are often referred to as "special emphasis" programs. While these programs do, indeed, receive special emphasis, each of the Institutes has in addition some half dozen or more areas which it describes as "new initiatives" or "high priority programs" or "special emphasis programs." These programs are highlighted because of the special health problems they represent or because of the special opportunities for progress they offer.

These concerns of the Institutes are often overlooked by those who think of the NIH activities mainly in terms of free-ranging research, and who regard the regular research grant as the Federal Government's chosen instrument for supporting medical research in academic institutions and hospitals. Since 1948, NIH has been highly successful in managing a rapidly expanding program in a way that subjected the academic community to a minimum of bureaucratic interference with its conduct of research. Despite the very considerable competence and high reputation of its own scientific staff and advisors, the NIH has never thought it appropriate--or, indeed, feasible--to attempt to direct the entire national medical research effort. On the contrary, NIH has always felt that in medical research the maximum freedom for the investigator is a condition for maximum creativity.

The effectiveness of the system is manifest, on the one hand, in the remarkable growth of American capability in the biomedical sciences and, on the other hand, in the tremendous advances in medical practice and in basic knowledge which the enhanced capability has brought about.

NIH's free-enterprise philosophy and the managerial system that has evolved from it have tended to obscure the fact that NIH is--and always has been--a mission-oriented agency with quite specific goals that it wishes to achieve. While its central task has been to build and sustain the national capability for medical research, its primary purpose, as an agency of the Department of Health, Education, and Welfare, is to improve the health of the American people.

In summary, the role of the Federal Government in support of research is to provide the tools and resources for the advancement of knowledge on behalf of human health and well-being and to broaden the base of that knowledge. It also helps create and sustain a climate in which biomedical research can flourish.

I know that that is the kind of climate that exists at these laboratories. I know that your goal is the fostering of creativity and the pursuit of excellence. That is why I have the highest hopes for the quality and significance of the work that will be done here.

I wish you every success as you embark on your important and life-saving mission.

TAB 4

4/95
THE ROLE OF THE FEDERAL GOVERNMENT
IN SUPPORT OF BIOMEDICAL RESEARCH

By

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To be presented at the International Endotoxin Conference,
Airlie House, June 1, 1972.

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TAB 5



694

A FAVORABLE OUTLOOK ON OPTOMETRY*

Robert Q. Marston, M.D.
Director
National Institutes of Health
Bethesda, Maryland

It is a great pleasure for me to participate with you in your Centennial Commencement Ceremony, marking a century of optometric education not only for the Illinois College of Optometry, but for the entire nation as well. As the oldest school of optometry in America, Illinois carries a long and distinguished record of achievement and service, and I was pleased to discover that nearly 40 percent of the practitioners in your profession are graduates of this school. This has been a century of birth, growth and maturity for your profession, as well as for your school. And it is appropriate today for us to consider the opportunities which now lie ahead for the members of this class and for the entire optometric profession.

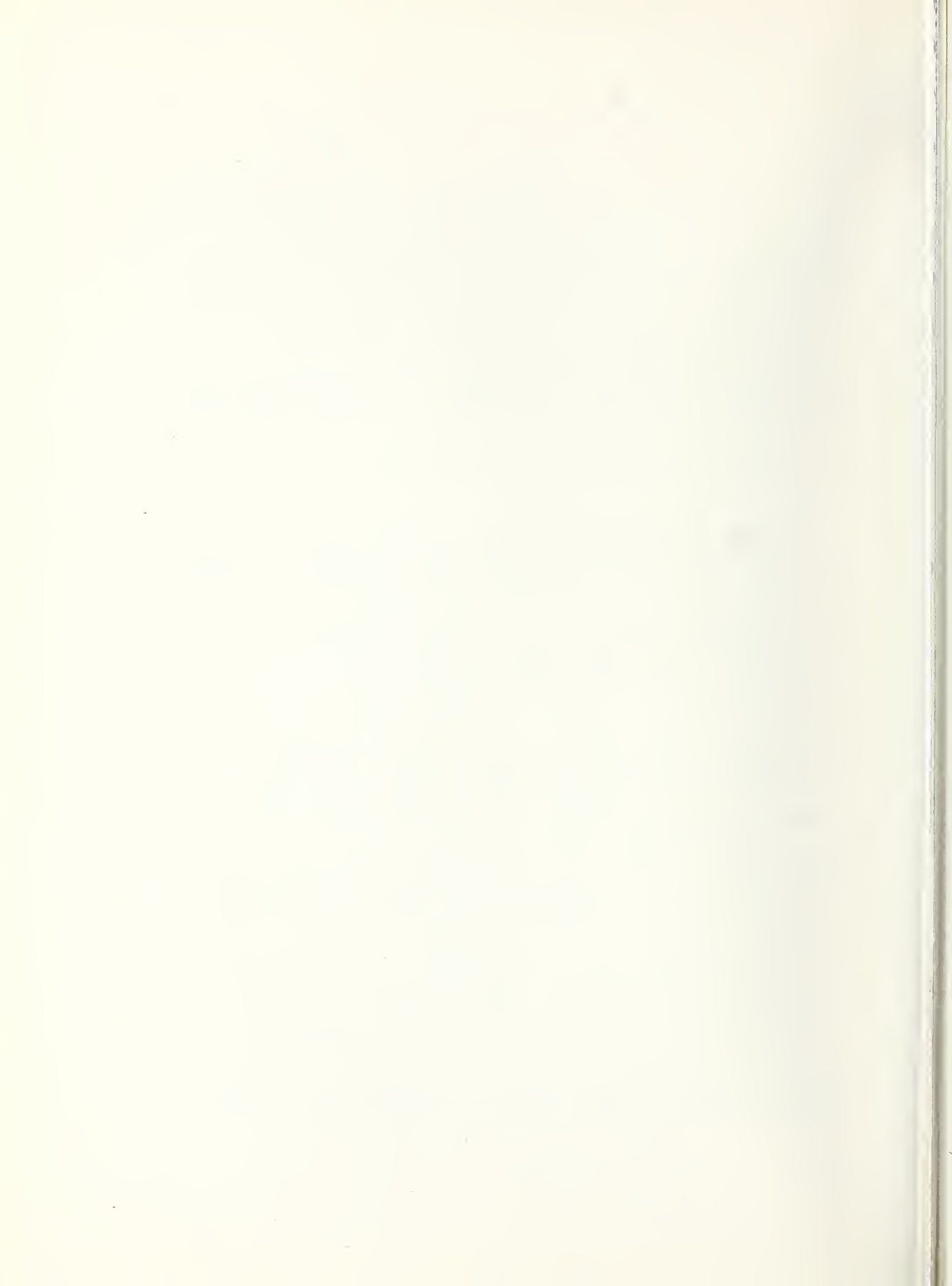
The 85 graduates here today have just completed a long and concentrated education and are about to begin their life's work.

To be presented at Illinois College of Optometry's Centennial Graduation Ceremony, June 4, 1972, Chicago, Illinois.



You have chosen a career that offers many rewards, both in satisfactions and security for yourselves and your families and in opportunities to serve others. Fortunately for all of us, you are among those whose career affords you the opportunity to practice your skills and apply your knowledge in a field where there is considerable need.

Almost as though it were a weather report or a horoscope, the Labor Department's new Occupational Outlook Handbook lists the employment prospects for the health professions: For optometrists, the chart shows "Favorable Outlook. Estimated Employment, 1970, 18,000. Average annual openings to 1980, 800." But what the publication does not say is that we will be graduating nearly 700 new optometrists this year, more than 100 fewer than the 800 annual openings we've just mentioned. Despite a growing number of optometrists practicing in this country, our ratio of optometrists per population remains at just slightly more than 9 per 100,000. The optimum ratio recognized by the American Optometric Association is one optometrist for every 7,000 persons, a rate of 14.3 per 100,000 population.



This is not the kind of situation that I would describe as "favorable" in outlook. It is certainly not favorable for the thousands of youngsters who are well into school before their vision problems are detected. It certainly isn't viewed as favorable by minority patients who can't help but notice that only a small fraction of the nation's optometrists are from minority groups.

Unfortunately, these and related problems are found throughout the health field. With more than 4½ million employees, the health industry has become the nation's largest employer. Our supply of health workers had doubled in just the past decade. Yet the problem of access to health care for vast numbers of our population does not seem to be greatly improved, if at all.

Since 1950, the number of physicians, for example, has risen by more than 100,000--to a total of about 334,000, yet we don't seem to have enough to go around. Nevertheless, the competition to get into the schools of the health professions is keener than ever, with thousands of qualified applicants being turned away.

It is only natural that people are beginning to ask why there is still a health manpower problem and wondering why the gains that have been made are not being felt in the community.

The causes of our health manpower problems, even though they may be familiar to you, are worth mentioning again, so you may judge how your own career plans can help improve the situation.

Much of the new manpower, of course, has gone simply to take care of the nation's rapidly rising health workload. Demands for health manpower have been increasing steadily with the size of the nation's population and increased consumer income. Other factors driving demands for health care upward have been the rising educational attainment of the public, expanded insurance coverage, and public commitments to extend health services through programs such as Medicare and Medicaid.

Trends within the health professions--toward specialization and away from the inner city and rural areas, where the needs are greatest--have tended to aggravate the problem. These problems

of numbers, location, and specialty are further compounded by serious racial imbalances. The nation's 23.5 million black citizens--11.5 percent of the population--are not only underserved in terms of health care, but in terms of their participation in the health professions they account for but 2 percent of the nation's physicians, 2.7 percent of the dentists and 5.7 percent of the professional nurses. Clearly there is much to be done to improve the motivation to enter the health field, to ease the economic pressures, and in some cases improve the quality of minority education which too often handicaps the minority student in competing for admission to the nation's health professions schools.

In this regard I was particularly pleased to note last fall that the American Optometric Association and its black counterpart, the National Optometric Association, began an active minority recruiting program. Participants at a meeting held here to launch the campaign faced squarely the fact that there are only about 150 black optometrists in the nation to serve the vision care needs of 22 million black people. I was interested that the

conference addressed the problem of increasing minority participation in optometry not only from the standpoint of adding to minority enrollment in optometry schools, but also recognized that the few minority optometrists we now have are not for the most part practicing in inner city or rural areas in the deep south.

Dr. Richard L. Hopping, President of the American Optometric Association, recently called further attention to this problem when he addressed the New England Council of Optometrists. Dr. Hopping said that white suburban optometrists should take on part-time responsibilities for urban optometric services. He called for the recruitment of minority city dwellers into optometry, the involvement of optometrists in planning community health care centers, and urged local optometric societies to help young optometrists in starting practices in underserved areas.

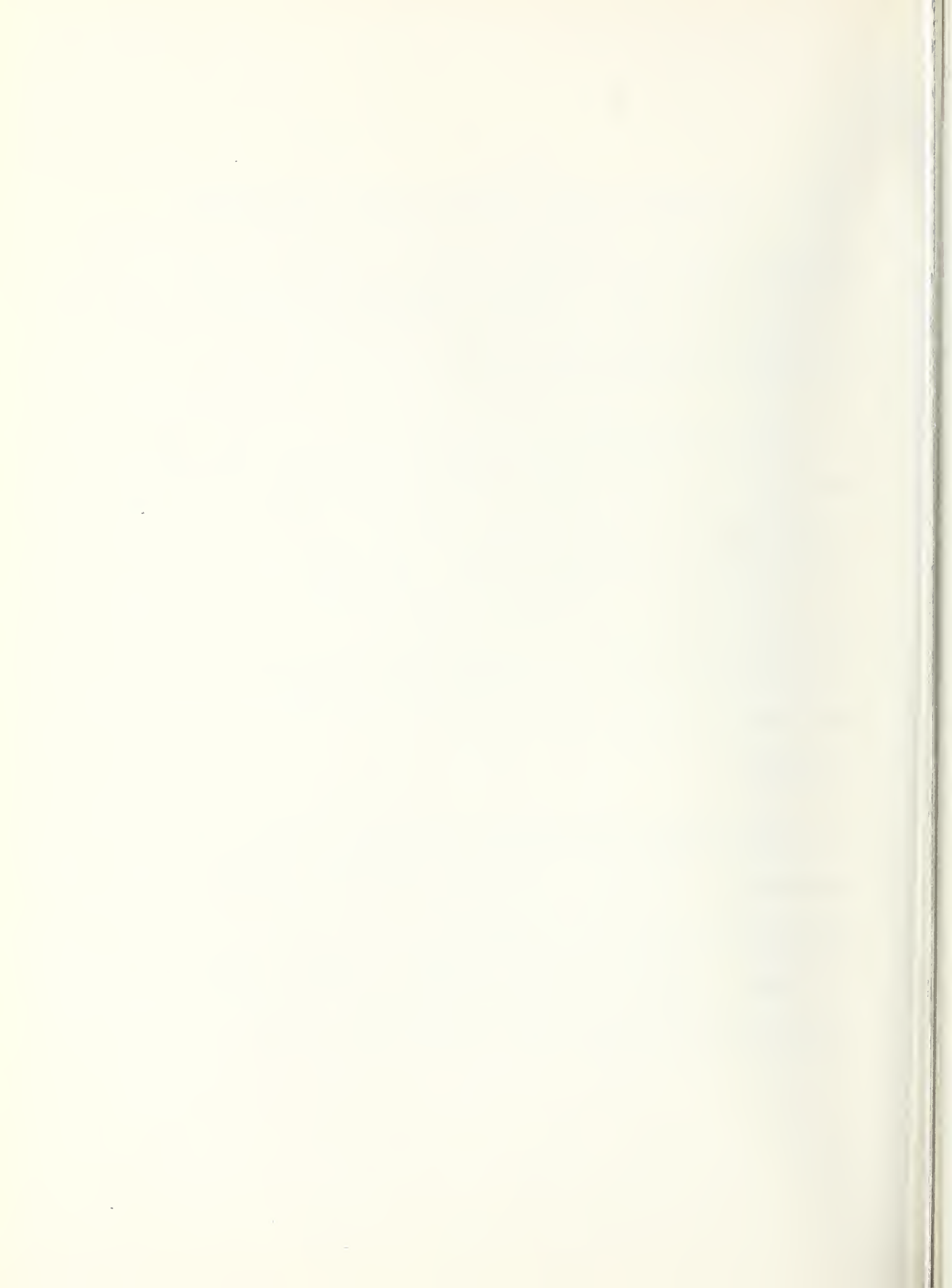
By its own admission, and in comparison with other health professions, optometry has come late to the realization of the



need for increased minority participation. But now the profession seems to be making up for lost time through actions which can only serve to improve optometry as a whole and add to its esteem and importance in urban communities.

It is quite evident that problems such as minority participation in the health professions and the distribution of health care are not going to solve themselves. But they can be solved if we work at them. The Comprehensive Health Manpower Training Act of 1971, enacted last November, gives us some of the tools. It contains several programs which will have an impact on the shape of your profession in the years to come.

To encourage the schools of the health professions--medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, and veterinary medicine--to expand their enrollments, the new law includes a capitation grant program. Schools now receive funds on the basis of their size of enrollment and their assurance to



expand by at least a given minimum. Bonuses are provided for schools which expand beyond the minimum levels. The Bureau of Health Manpower Education reports that a number of schools of optometry have already responded to this incentive. All 12 of the schools have applied for the capitation grants, which requires them to assure a minimum increase of enrollment. Two have indicated they will exceed the minimums in order to qualify for bonus funds.

The Act also supports the construction of health professions schools through grants, loan guarantees, and interest subsidies.

This expands an effort which was begun in 1964. Construction awards to schools of optometry during the past eight years have totaled more than \$7 million and made possible the addition of 181 first-year places. Since 1966, institutional grants and special project grants to schools of optometry have amounted to more than \$14.5 million to help finance and improve existing optometry programs. Since 1967, 1,115 optometry students have received scholarships totaling more than \$750, 000 and loans of more than \$3.8 million to finance their education.



Loan and scholarship assistance to the student has been increased, with maximums now raised to \$3,500 a year. Loan forgiveness provisions have been added for students who agree to practice in shortage areas. There are new programs to train teachers in the health professions, and new Health Manpower Initiative Awards to finance health education for underserved areas.

This last group of awards provides a minimum of \$5 million annually to encourage minority students to pursue health careers and to help qualify those students for entry into the professional schools. It also includes support for projects to encourage new or more effective approaches to the organization and delivery of health services in underserved areas.

This important legislation is just the latest chapter in the Federal effort to solve the nation's health manpower problem. The transfusion of more than \$1.4 billion over the past nine years into the schools of the health professions has helped invigorate them to the greatest spurt of growth, improvement, and innovation since the modern system of health professions education was established.



Two new schools of optometry have been established in the past decade, and the number of optometry graduates has risen from 300 ten years ago to about 700 today.

Within the schools the trend is toward shortened curricula, more electives, the integration of educational goals with the needs of the community, and the development of auxiliary manpower. In addition, the schools of optometry have expanded their range of concerns to include work with such groups as brain-damaged children, geriatric patients and juvenile delinquents.

Our manpower experts tell us that in the field of optometry, we may see a much wider use of auxiliary personnel. They expect a growing emphasis on trained assistants and aides to augment the professionals in the delivery of services.

The development of this profession cannot be considered in a vacuum, however. Long established roles within the health professions are going through some rather rapid changes, and the issues and problems related to these changes cannot be sidestepped.



Many of these issues will be resolved during the next several years--and the outcome will reflect not only how much your profession can contribute to the provision of health services but how effectively you make your contributions and potentials known to the assorted agencies and institutions who collectively are determining the shape of the health professions for the future.

Optometrists are already represented on such governmental advisory groups as the National Advisory Council on Health Professions Education, the National Advisory Eye Council of the National Eye Institute, and the National Highway Safety Advisory Committee. I know that optometry representatives are working very hard to gain additional representation for your profession in programs which are relevant to your concerns.

The increased efficiency that comes from proper utilization of auxiliary personnel is undeniable and substantial. More important, however, auxiliaries also influence the quality of care you are able to deliver to your patients. The Bureau of Health Manpower Education believes that all branches of health



care will experience the same benefits as those who have already made the effort to examine their practice critically, to determine those activities which do not require the extensive expertise of the highly trained practitioner, and to teach someone else to carry out those functions.

Any avenue that promises to improve efficiency, maintain the quality of care, and produce savings must be explored. And this search for efficiency must go on among the various professions as well as within the individual specialties. I do not propose to prescribe the relationship that should exist between medicine and optometry, for example, nor do I wish to advocate any specific proposal at this time. But I think we must recognize that the relationships among the health professions are indeed changing. They change as a result of the rising health demands of a growing public; they change as a result of inadequacies within the health professions--inadequacies of numbers, geographic maldistribution and the maldistribution among the various medical specialties; and finally they change as we find better ways of doing things.



The scope and interests of the professions themselves are changing, as well. Witness the evolution of optometrists from Renaissance spectacle-makers into today's vision care specialists concerned with problems ranging from industrial visual efficiency to rehabilitation of the partially sighted. The key to maintaining and developing excellence in any scientifically based endeavor is advanced education and research. Without an active research component any health profession stagnates, teaching becomes pedantic and boring, and the quality of care at best remains at status quo. With its concern for increased professionalism, modern optometry has recognized the importance of research, exemplified by the research programs at the various schools of optometry and the formation of the American Academy of Optometry and the American Optometric Foundation.

Yet it is true that the great majority of entering optometric students have no thought of pursuing careers in academic optometry or optometric research, nor does such an interest develop during their academic training. Two few receive the kind of training which would enable them to conduct vision research. Yet



research opportunities for those with optometric training is potentially great. Their special skills could be brought to bear upon a number of important problems including the scientific evaluation of low vision aids, the development and evaluation of automated vision testing devices, and studies of the vision requirements of jobs and everyday activities and their bearing on the abilities of the partially-sighted.

I understand that the staff of our National Eye Institute has recently been engaged in discussion with representatives of the optometric research community to explore ways of expanding and intensifying optometric research and to increase the potential for NIH support of such activities.

And so the outlook for your profession is favorable--favorable in terms of opportunity and the excitement of innovation and change.

Just as no single factor can account for our health care problems, neither can we expect to solve them through one approach. Nor can we expect one group within the health community to shoulder the entire responsibility for solving even



all the limited problems within the group's purview. But we can look to this class and ask and hope for a breadth of thought that recognizes the vastness of the health field, its capacity for serving the public, and the significant increase in that capacity if we will all cooperate in the development of viable, improved approaches to providing health care.

In your practice, through your organizations, as concerned and capable citizens of your community, I am sure you will utilize every measure of skill and wisdom you have gained in your years of education, in the fine tradition of this century-old school. A continued education--and the opportunity for service--lie ahead. I congratulate you and wish you well.

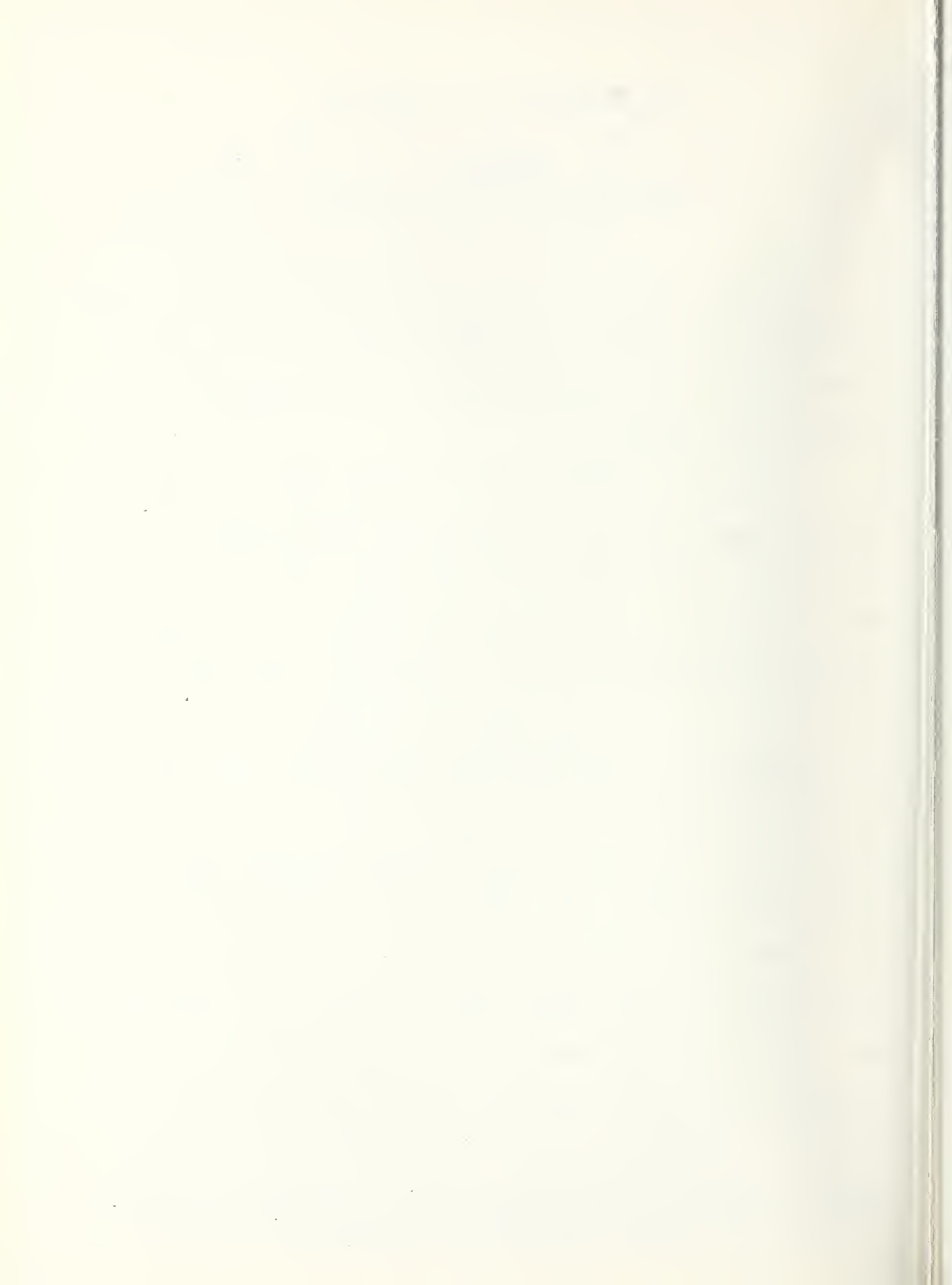
OLD TRUTHS IN NEW WRAPPINGS*

Robert Q. Marston, M.D.
Director
National Institutes of Health
Bethesda, Maryland

Members of the graduating classes, your families, Board of Trustees, Dr. Cameron, President Shober, Deans DiPalma, Devlin, Bandi, Representative Flood, other distinguished guests, ladies and gentlemen.

The age-old rhythm of man's struggle with life and death, the ebb and flow of the tides and other natural phenomena, and the sameness of commencement addresses across this country at this time of year are unlikely to be markedly changed by what happens here in Philadelphia during the next hour or so. But the pause which we are taking to honor and to recognize and to wish well those who move out into the health fields does constitute a high order of seriousness. Indeed in the 25 years since my own graduation from medical school, during which I have attended about the same number of commencements in one place or another, I continue to be struck at each by the willing roles played by wives, husbands, and children and other members of the family in making the long and often costly education possible, by the sense of anticipation following a long and generally tough period of

*To be presented at 125th Commencement at Hahnemann Medical College and Hospital, Philadelphia, Pennsylvania on June 8, 1972.



training by the graduates themselves, and by the sense of significant accomplishment which marks commencements in the health sciences as somewhat different from commencements in general.

I am pleased to be with you to share in your own private thoughts and pride in this graduation but also to invite you to look more broadly at this commencement to see it a bit perhaps as I do, as a Federal official who during the past half dozen years has served at the national level across the spectrum of biomedical research, education in the health area, and at an earlier stage in the Federal programs involving the organization and delivery of health services. Viewed from this perspective, as my title suggests, I find that the truths remain very much the same but the way in which they are packaged or wrapped may give us trouble sometimes in seeing the contents because of the glitter of the wrappings. A writer seeking headlines might summarize what I intend to say to you today as follows: Marston cautioned against targeted programs in biomedical research, against excesses of the new consumerism, and he worried that too much money might corrupt the medics. I have indeed chosen to speak on these matters but my most important message is that you're



exquisitely educated in substantive matters and that your main prospect for contributions lies in the low profile of expertise. While as humans we are all, thankfully, also creatures of emotion with hopes and desires--some realistic, some not--this commencement exercise certifies that you have an unusually cultivated intellect. Recall that Horace Mann in 1848, in the very year that Hahnemann College was founded, asserted, "Without a cultivated intellect, man is among the weakest of all the dynamic forces of nature; with a cultivated intellect, he commands them all."

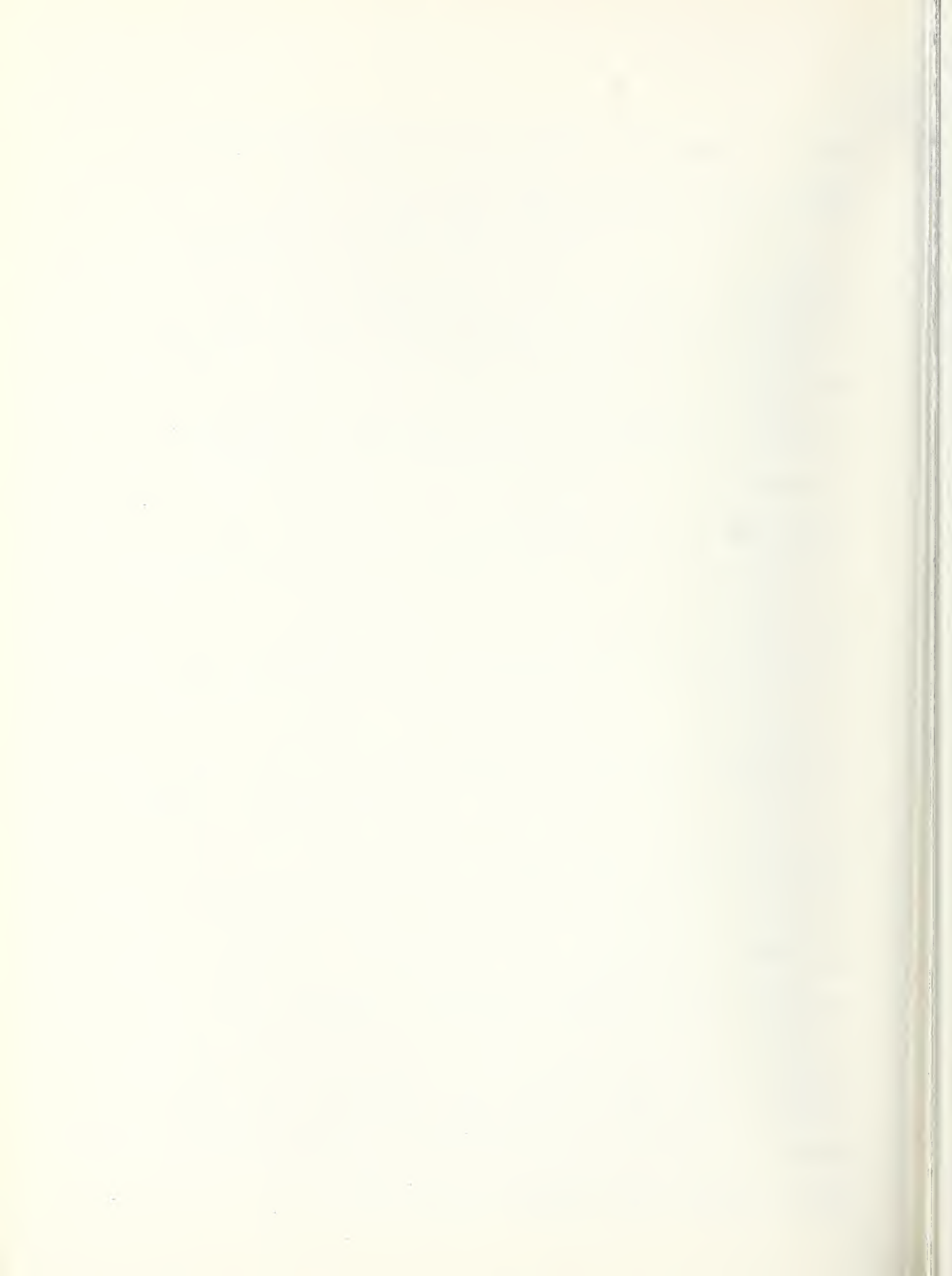
Let me turn first to speak about the usefulness of science in the medical field--what things it can do and what things it cannot do; secondly, to talk about the new consumerism--its strengths and some of its weaknesses; and third, to focus on the hopes and fears of the American people--in general, and in matters of health specifically.

Science and Medicine

The discovery of the power of the experimental approach may indeed prove to be the dominant feature of the 20th Century. The experimental approach is the most powerful instrument for seeking the truth. Former Chief Justice, Charles E. Hughes

stated it very well at the American Association for the Advancement of Science Annual Meeting in 1925:

"If to an increasing degree we have the security of sound public opinion, if the extravagances and diatribes of political appeal fail of their object, and if, notwithstanding the apparent confusion and welter of our life, we are able to find a steadiness of purpose and a quiet dominating intelligence, it is largely because of the multitude of our people who have been trained to a considerable extent in the scientific method, who look for facts, who have cultivated the habit of inquiry and in a thousand callings face the tests of definite investigations. With scientific applications on every hand, the American people are daily winning their escape from the danger of being fooled...We need your interest in knowledge for its own sake; the self-sacrificing ardor of your leaders; your ceaseless search for truth; your distrust of phrases and catch-words; your rejection of every plausible counterfeit; your willingness to discard every disproved theory however honored by tradition, while you jealously conserve every gain of the past against madcap assault; your quiet temper, and, above all, your faith in humanity and your zeal to promote the social welfare. We need your horizon, your outlook on the world."



But on the other side of the coin is to expect unrealistically the experimental approach to solve all human problems. Even in the area of disease where the experimental approach has produced such brilliant benefits many problems are not science-based. These would include cancer associated with cigarette smoking where motivation, not new knowledge, constitutes the deficit. In some hereditary diseases it seems unlikely that any methods other than selective exclusion of marriages will be effective. And some aspects of pollution and environmental problems will depend primarily on social trade-offs, rather than on the development of new knowledge. In general, the really serious problems of man have been resistant to drastic political and economic remedies and in contrast there have been dramatic successes in research and technology, and as a result of these successes there is a growing demand that science solve the problems of humanity, even when there are questions that cannot be answered by science.

I spoke at some length on this subject at Woods Hole about a year ago. Alvin Weinberg has characterized this same theme as the need to distinguish between science and what he calls trans-science. While I have tended to use examples from the medical field, he has used examples from his own field of nuclear energy. For example, he points out that in the

Important matter of setting acceptable standards for low levels of radiation, it would take 8 billion mice to establish a scientific answer, a number so large that clearly we have used and will use other ways at arriving at an answer. But in addition to those conditions in which he finds that science is inadequate simply because to get the answers would be unrealistically expensive, he also argues that science may be inadequate because the basic subject matter is too variable, such as in the social sciences, to allow rationalization according to the strict scientific criteria established within the natural sciences. Then too, science may be inadequate simply because the issues themselves involve moral and esthetic judgments, rather than scientific truths.

As we move into what is likely to be a period of even more active criticism of those in the health professions, it is essential that there be a clear understanding of the nature and limitation of the role of medical research in solving health problems.

We are NIH are committed to carry out as effectively as possible not only those high emphasis programs growing out of an expert consensus of scientific opportunity, but also those programs where social need or public hopes are stronger forces in targeting than scientific leads. Population research,

sickle cell anemia, arteriosclerosis and cancer are examples where mixture of both need and opportunity exists. There is, however, a tendency to confuse the new package--the targeted research program--as different in kind, less dependent on creative individuals and less dependent on strict use of the experimental method. Here the package must not be confused with the substance. The experimental method helps to find truth, not necessarily a social remedy, and experiments come out as they come out, not as we want them to come out.

The New Consumerism

I just mentioned that we are entering a phase of medicine in which I believe health professionals as individuals, and as groups, will come in for their greatest criticism since Hippocrates. Consumerism has extended far beyond thrifty bargaining at the market place. The movement has brought into question institutions, agencies, professions, and industries, and in many cases, rightly so. One effect of the questioning already is to expose the individual physician and the profession as a whole to a level of criticism unlike that experienced by the physician in modern times. You and your professional colleagues will experience this new adversary relationship in confrontations ranging from threats of personal malpractice suits



to the questions "Why can't you cure my disease?" or "Why should you get rich off of my pain?" A simple defense could be to engage in a defensive practice of medicine, prescribing extra laboratory tests and X-rays and unnecessary consultations more for your own protection than for the patients. You likely will find discouragement, disappointment that your altruism and above-average workload in entering this field of service seem to go unappreciated.

In the past, medical students and other health workers were warned to avoid becoming trapped in a self image of God-like proportions. Remember for instance, Robert Louis Stevenson's words, "There are men and classes of men that stand above the common herd: the soldier, the sailor, and the shepherd not infrequently; the artist rarely, rarelier still, the clergyman; the physician almost as a rule. He is the flower (such as it is) of our civilization; and when that stage of man is done with, and only to be marvelled at in history, he will be thought to have shared as little as any in the defects of the period, and most notably exhibited the virtues of the race. Generosity he has, such as is possible to those who practice an art, never to those who drive a trade; discretion, tested by a hundred secrets; tact, tried in a

thousand embarrassments; and what are more important, Heraclean cheerfulness and courage. So that he brings air and cheer into the sick room, and often enough, though not so often as he wishes, brings healing." Most or perhaps all of you were attracted into medicine, as I was, with some of the feeling of what Stevenson is saying. As one who has strayed into the area of public administration where criticism, fair and unfair, is well within the rules of the game, let me alert you to the shock that you well-motivated and conscientious people may be facing--for your moral test will be in your reaction to it. I hope you can avoid cynicism which can be more destructive than egotism. I hope you will not allow yourselves to become entrenched in blind defense of the status quo. In that direction is stagnation. But there is, as always, the other side of the question. When does consumerism intrude inappropriately into the area of expertise? The package labelled consumerism does not automatically insure truth. Selfish people for personal advancement fly under its banner but I am even more concerned about the misguided but well-motivated who feel that a pure heart can substitute for ignorance, an honest tongue for lack of competency and clever criticism for substantive contributions. Beware of those who seek only to destroy, not build, of those

who depend only on the heart, not the mind in matters of health, but at the same time be alert to the truths that they also speak--that medicine is for people, not for doctors, or other health professionals and not for institutions or intellectual enjoyment.

The Hopes and Fears of Americans

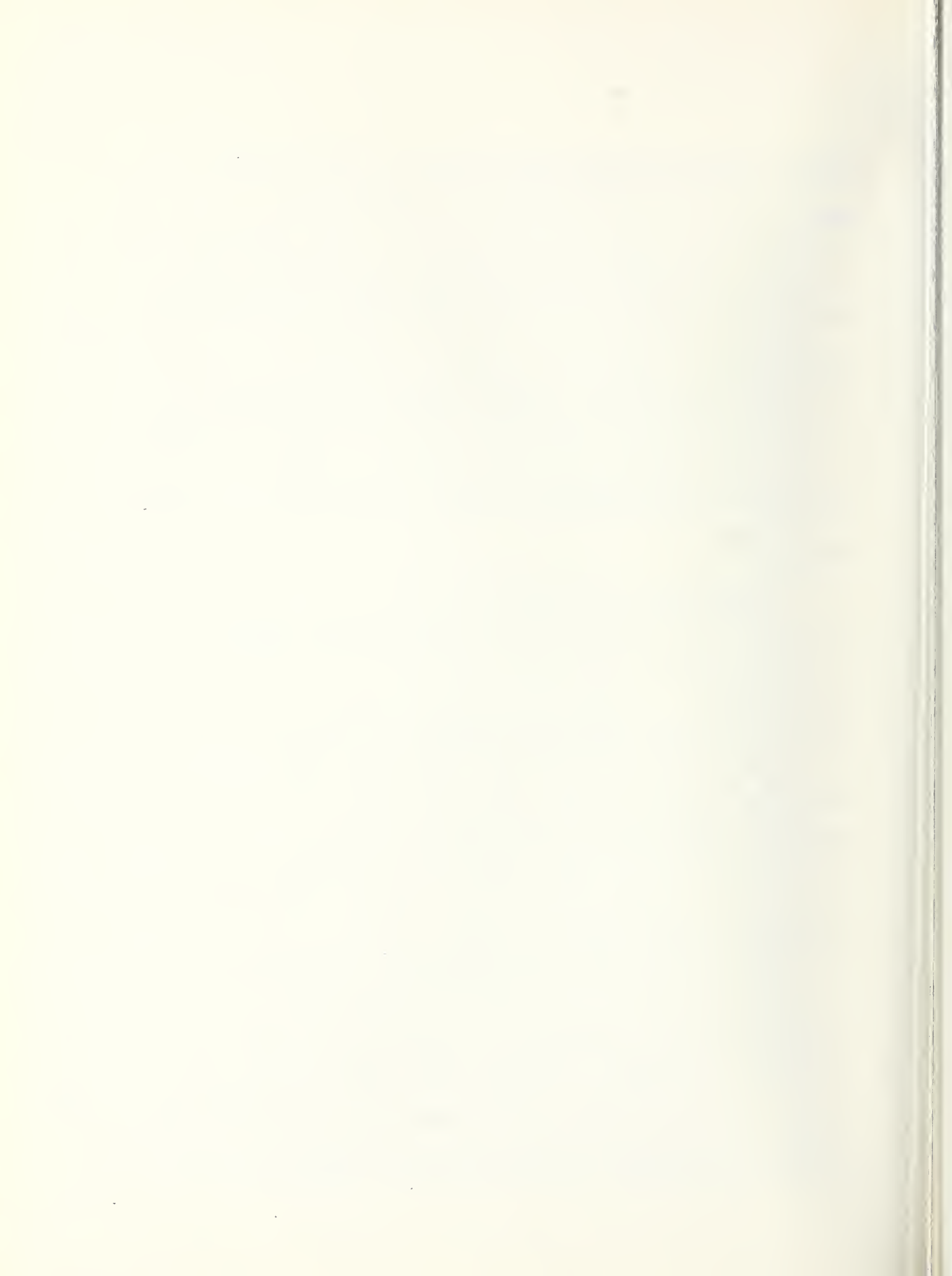
The last area I want to discuss has to do with the hopes and fears of the American people as they apply to health. Let me start with the summary of two public opinion surveys carried out in January and April of 1971 and published under the titles of "Hopes and Fears of the American People" by Cantrell and Rall. The pertinent conclusions for my purposes are:

1. The American people believe their nation is in trouble. They feel that the United States has slid backward over the past five years.
2. Public anxiety over the state of the nation focuses particularly on tensions and diversions among its citizens. Almost one in every two Americans sees these tensions as serious enough to "lead to a real breakdown in this country."
3. The public does not dismiss this national unrest as simply the work of radicals and troublemakers. Sizeable

numbers sense systemic causes related to the quality of leadership and the performance of institutions.

4. In contrast to the above, the hopes and fears of the American people about their own lives reflect general satisfaction. There is a lessened reference to many traditional material aspirations--a higher standard of living and owning a home, for example--which may indicate overall contentment and assumption of fulfillment of much of the traditional American Dream.

The authors of this book point out that nothing is so elusive in the analysis of the contemporary America as the mood of its people. I shall do no more than call your attention to these conclusions about the nation as a whole because this is outside my area of expertise. But I will use this as a starting point by saying that in the field of medicine one can characterize that period between 1965 and 1975 as a period in which awareness of various health problems grew. Public anxiety from a variety of sources focused on inaccessibility, high cost and a growing confusions over the apparent incompatibility between modern miracles of health on the one hand, and the failure to resolve human health problems on the other hand. Remember that in 1965 medicare, medicaid, regional medical programs, comprehensive



health, health research resources and the second phase of the health professions education act which for the first time gave direct assistance to educational institutions were all passed. Much additional legislation as promissory notes to the American people has passed in succeeding years--most recently, the comprehensive health manpower legislation of 1971, the new Cancer Act of 1971, the new Heart Act, probably destined to be passed within the next few weeks and many others. Not only has there been a probing within the Executive and Congressional branches of Government, but a cry of the times has been if we can put a man on the moon, let's cure cancer. Another has been the equally misguided suggestion, let's stop all research and use that money to cure people. Another trend has been the increasing anticipation that nothing short of major changes in financing, in distribution, and in organization, can be expected over the new few years. The national request for more health workers has led to increasing numbers of young people heading for health careers, especially as the job market in engineering and physics and school teaching seems to be constricting. It's led also to another serious dilemma. We are dependent on the



graduates of foreign medical schools at the same time we are turning away increasing numbers of qualified Americans from career opportunities in medicine. I do not think this country will long tolerate this situation.

Against this background of increasing dissatisfaction which some have called a national health crisis, there is a contrasting view similar to that in the general national survey which noted a general personal contentment because across broad areas of middle America, as some would call it, there is much to suggest a greater contentment with the minor inconveniences of today than with the radical and untried social experiments some have suggested. In health as in other fields those who have it made may want to keep it that way. Against this background, the health worker can be easily trapped. On the one hand, he's a have--perhaps the most have of all--from some of the statistics on job and income estimates. However, he is sworn by all that is decent in the whole history of mankind not to distinguish between the rich and the poor, the powerful and weak in matters of health. If I were completely honest with you and commencements are times for honesty, I might suggest that those of us in Medicine think seriously about the quotation "it is easier for a camel to pass through the eye of a needle than for a rich man to enter heaven." You have entered an intellectually and highly

dedicated profession. The pursuit of worldly good will not suffice and while there is no need for you to avoid a reasonably comfortable life, you have been so conditioned by the need to provide meaningful and significant service and to use your minds in an intellectual and creative fashion that there are no effective alternatives to these ego needs which you have by nature and have further augmented by your education and experiences.

Today I ask you to continue to look at the contents not the wrappings. Cling to and use well the old truths in science and in professionalism, but at the same time, listen to the changing needs and even to the new truths of our people. I have been an advocate for change most of my life, although today as Director of that very sound ship, the National Institutes of Health, I find myself cast more in the role of a defender than at sometimes in the past. I urge you, too, to be an advocate for change constructively, recalling that you leave an institution with a rich tradition in the ability to change to meet new demands. Indeed President Cameron in his brief sketch in your annual bulletin characterizes Dr. Samuel Hahnemann by the word "reformer." Congressman Flood and his powerful appropriation subcommittee can tell you better than I there are serious demands for change to meet the growing needs of the American people in

the area of health. But neither he nor his committee nor the Congress nor the Executive Branch nor the people of this great nation are the least bit interested other than in the best that you can deliver. Treat them and those of us in the Federal Government kindly but firmly as we seem to push you in directions which you know not to be in our best interest. Be suspicious of our fancy wrapping as you are of those I have mentioned.

And now in closing, let me carry out the one really delightful function that a Commencement Speaker has and that is on behalf of all of us, in this room, express our warmest congratulations and best wishes to you who graduate today, and further in a perhaps selfish and parochial sense, let me hold out my hand to welcome you into the exciting field of medicine and to say how much we need your help.

Congratulations!



TAB 7



6/20/72
9:00 a.m.

I called Dr. Ed Rall's office for speech given by Dr. Marston on Sunday, June 18th at the Congress of Endocrinology. Dr. Marston said, after he delivered the speech, he gave the paper to Dr. Rall.

Dr. Rall's office will forward the speech when Dr. Rall returns to the office --after the meetings on Endocrinology are over this week. Dr. Marston said he had made a few minor changes.

Lib Fuller would like a copy of the speech and Carol Cone would also like to have one for their records.

Verda:

6/21/72

The Press represented at the Endocrinology Meeting on Sunday asked to have a copy of Dr. Marston's remarks. Dr. Marston left his copy with Dr. Ed Rall and told me to have Dr. Rall handle this. I understand the speech was given to the press, with a few minor changes, but nothing too extensive. This is a copy of the one I kept for our files. I gave one to Lib and one to Carol Cone for their files.

cpj

cc Mr. Whelan
✓ Mr. Carrigan

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LADIES AND GENTLEMEN—IT IS A PLEASURE TO MEET WITH SUCH A DISTINGUISHED GROUP OF SCIENTISTS AND PHYSICIANS, AND TO SHARE WITH YOU SOME OF MY CONCERNS. FIRST, I SHOULD LIKE TO COMMENT UPON THE GROWING PUBLIC INTEREST IN FAIRLY SPECIFIC ASPECTS OF BIOMEDICAL RESEARCH AND, STEMMING IN PART FROM THIS INTEREST BUT SURELY AUGMENTED BY THE LARGE BUDGET FOR BIOMEDICAL RESEARCH TODAY, THE EXTENSIVE DISCUSSIONS ABOUT TARGETED OR APPLIED RESEARCH VERSUS BASIC RESEARCH.

I BELIEVE THAT THE PREPONDERANT MAJORITY OF WORKING SCIENTISTS IN THIS AND OTHER COUNTRIES WOULD AGREE THAT THE SUREST COURSE TO PROGRESS IS TO PROVIDE OPTIMAL TRAINING AND ADEQUATE SUPPORT FOR THE MOST TALENTED AND TO GIVE THEM MAXIMAL INTELLECTUAL AND OPERATIONAL FREEDOM.

SOME OF THE GREATEST ADVANCES WITH THE BROADEST IMPLICATIONS HAVE EMERGED FROM SINGLE MINDED CONCENTRATION ON THE ESSENCE OF A PROBLEM AS SUCH--TO THE EXCLUSION OF ANY CONCERN ABOUT RESULTS OF ITS SOLUTION.

IN DESCRIBING HIS ATTITUDE TOWARD HIS WORK ON PENICILLIN, FLOREY MADE AN ALMOST UNBELIEVABLE STATEMENT, "I DON'T THINK THE IDEA OF HELPING SUFFERING HUMANITY EVER ENTERED OUR MINDS."

ONE SENSES OVER-MODEST UNDERSTATEMENT HERE AKIN TO THAT EXPRESSED IN FLOREY'S LAST RECORDED REFERENCE TO THE SUBJECT WHEN HE SAID, "WE HAD A BIT OF LUCK WITH PENICILLIN--A GREAT DEAL OF LUCK."

AGAINST THIS HIGHLY INDIVIDUALIZED VIEW OF THE HISTORY OF THE PROGRESS OF BIOMEDICAL SCIENCE, A VIEW SERIOUSLY TO BE CONSIDERED, WHAT

DELIVERED BY ROBERT Q. MARSTON, M.D., DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH, BEFORE THE IV INTERNATIONAL CONGRESS ON ENDOCRINOLOGY, JUNE 18, 1972, WASHINGTON, D. C.

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CAN WE SAY ABOUT TODAY'S DEVELOPMENTS AT THE POLICY LEVEL?

IN THE SPRING OF 1972, IN THIS COUNTRY AND WORLD-WIDE, WE HAVE MOVED TO A CONSIDERABLE DEGREE AWAY FROM "INDIVIDUAL" SCIENCE AS I HAVE DESCRIBED IT TO A GREATER DEPENDENCE UPON WHAT HAS BEEN CHARACTERIZED AS PROGRAMMED OR ORGANIZED OR TARGETED RESEARCH. SUCH TARGETED RESEARCH IS TO BE DISTINGUISHED FROM DEVELOPMENT OR TECHNOLOGY, WHICH IS YET ANOTHER PROCESS. THE SEARCH IS STILL A SEARCH BUT IT HAS BEEN PROGRAMMED AND HAS A STRONG ELEMENT OF EXTERIOR DIRECTION.

IF ONE LOOKS ABROAD, THE MOST COMMON QUESTIONS OF SCIENCE POLICY ACROSS A WIDE RANGE OF GOVERNMENTAL AND POLITICAL FORMS IS NOT WHETHER BUT HOW CAN BASIC BIOMEDICAL RESEARCH BE TARGETED MORE EFFECTIVELY ON RECOGNIZED HEALTH PROBLEMS.

I HAVE JUST RETURNED FROM THE USSR WHERE SERIOUS CONCERN WAS EXPRESSED ABOUT HOW EFFECTIVELY AND EFFICIENTLY TO CARRY OUT NATIONAL RESEARCH PROGRAMS IN VIEW OF THE CONSIDERABLE DEGREE OF REGIONAL AND INSTITUTIONAL FREEDOM OF CHOICE WHICH EXISTS THERE.

A YEAR-LONG DEBATE HAS BEEN GOING ON IN THE UNITED KINGDOM WHICH IN ESSENCE RELATES TO THE CONTINUED AUTONOMY OF GOVERNMENT-SUPPORTED SCIENCE. THE ARGUMENTS FOR CHANGE AND FOR MAINTAINING THE STATUS QUO ARE REFLECTED IN THE ROTHSCHILD AND DAINTON REPORTS AND THE RESOLUTION OF THESE POLAR POSITIONS IS EXPECTED SOON.

IN THIS COUNTRY, THERE HAS BEEN MUCH DISCUSSION FOR MANY YEARS BUT THE CANCER DEBATE OF LAST YEAR SYMBOLIZED, MORE THAN ANY OTHER SINGLE EVENT, THE INCREASING POLARIZATION BETWEEN CENTRALLY ORGANIZED LARGE-SCALE TARGETED RESEARCH ON THE ONE HAND AND DECENTRALIZED INVESTIGATOR-INITIATED RESEARCH PROPOSALS SELECTED FOR SUPPORT THROUGH A PROCESS OF

PEER REVIEWS ON THE OTHER. YOU WILL RECALL THAT ALL WHO SPOKE ON THIS PROBLEM AGREED THAT THERE WAS A NEED FOR BOTH, AND THAT THE QUESTION WAS ONE OF APPROPRIATE BALANCE.

LET ME NOW SHIFT EMPHASIS TOWARDS THESE PROBLEMS AS THEY RELATE TO ENDOCRINOLOGY. IN PARTICULAR I SHOULD LIKE TO EMPHASIZE THE CONTRIBUTIONS THAT ENDOCRINOLOGISTS CAN MAKE TOWARDS THE AMELIORATION OF CERTAIN PRESENT SOCIETAL PROBLEMS.

CERTAINLY ONE OF THE PRIMARY PROBLEMS THAT FACES SOCIETY TODAY IS A CONSTANTLY INCREASING POPULATION. ALTHOUGH MALTHUS A HUNDRED YEARS AGO MAY WELL NOT HAVE BEEN TOTALLY CORRECT IN SOME OF HIS ASSUMPTIONS, I THINK IT IS BEYOND QUESTION THAT RESOURCES OF THE PLANET EARTH ARE FINITE AND REPRODUCTIVE CAPABILITIES OF ALMOST ANY ORGANISM ARE ESSENTIALLY INFINITE. THEREFORE, AT SOME TIME THE NUMBER OF PEOPLE WILL EXCEED THEIR RESOURCES, OF WHICH FOOD AND HOUSING ARE ONLY THE ESSENTIALS. ALREADY IN LARGE AREAS OF THE WORLD THE POPULATION HAS CLEARLY OUTSTRIPPED THE CAPACITY OF SOCIETY TO PROVIDE ANYTHING APPROXIMATING THE AMENITIES NECESSARY FOR A CIVILIZED LIFE. TODAY THE MOST IMPORTANT MEASURES WHICH HAVE BEGUN TO AFFECT POPULATION GROWTH HAVE BEEN THOSE CONTRIBUTED BY ENDOCRINOLOGISTS. I AM SURE IT IS UNNECESSARY TO RECALL TO YOU THE EARLY WORK OF P. E. SMITH, HERBERT EVANS, ALLEN, ZONDEK AND ASCHHEIM AND THE OTHERS WHO IN THE EARLY TWENTIES, THIRTIES, AND FORTIES DEMONSTRATED THE INTERDEPENDENCE OF THE OVARY AND THE PITUITARY. THE WORK OF BROUHA AND SIMONNET IN PARIS AND HISAW, MEYER, MOORE AND PRICE IN THIS COUNTRY LAID THE GROUNDWORK FOR ATTEMPTS TO INHIBIT PITUITARY SECRETIONS WITH CERTAIN ESTROGENIC COMPOUNDS AND THEREBY INHIBIT OVULATION. THE FINAL STEPS

IN THIS PROCEDURE CAME WHEN THE LATE GREGORY PINCUS AND ROCK UTILIZED THESE CONCEPTS TO FORMULATE AN ESTROGENIC PROGESTATIONAL MATERIAL WHICH COULD BE TAKEN BY MOUTH AND WHICH WOULD INHIBIT OVULATION. DRAMATIC AND IMPORTANT STATISTICALLY AS THE ORAL CONTRACEPTIVES ARE TODAY, I AM SURE YOU WILL AGREE WITH ME THAT WE HAVE STILL A LONG WAY TO GO TO OBTAIN A MATERIAL WHICH IS TOTALLY SAFE, WHICH IS INEXPENSIVE, AND WHICH CAN READILY BE TAKEN INFREQUENTLY AND WITH LITTLE INSTRUCTION. I WOULD HOPE THAT THE KNOWLEDGE CURRENTLY BEING GATHERED MAY GIVE US OTHER POSSIBILITIES OF INTERRUPTING GERM CELL PRODUCTION OR DELIVERY IN EITHER THE MALE OR FEMALE. I AM DELIGHTED TO SEE PAPERS AND SYMPOSIA ON SPERMATOGENESIS AND CONTROL OF PITUITARY SECRETIONS BY HYPOTHALAMIC PRINCIPLES. I THINK SOCIETY OWES A MAJOR DEBT TO ENDOCRINOLOGISTS FOR THEIR PRELIMINARY AND IMPORTANT WORK IN PRODUCING MATERIALS WHICH EFFECTIVELY CONTROL FERTILITY, BUT I WOULD ONLY DRAW YOUR ATTENTION TO THE FACT THAT THE WORK IS AS YET INCOMPLETE. FROM WHERE I SIT, IT SEEMS LIKELY THAT IT WILL BE UP TO ENDOCRINOLOGIC INVESTIGATION TO DISCOVER MORE EFFECTIVE, CHEAPER AND SAFER CONTRACEPTIVES.

I MUST ALSO MENTION THE WORK OF ENDOCRINOLOGISTS IN ANOTHER SOCIETAL PROBLEM RELATED TO POPULATION, BUT RELATED TO POPULATION IN THE INVERSE WAY, NAMELY THE PROBLEMS OF INFERTILITY AND FETAL SURVIVAL WHICH HAVE BEEN SO RESISTANT IN PAST YEARS TO MEDICAL INTERVENTION OF ALMOST ANY SORT.

THE POSSIBILITY OF TREATMENT OF INFERTILITY IN WOMEN WITH THE USE OF GONADOTROPINS IS CERTAINLY DRAMATIC AND IMPORTANT. THE SENSE OF SECURITY THAT WOMEN ARE BOUND TO HAVE WHEN IT IS KNOWN THAT MANY CASES OF INFERTILITY MAY BE TREATED SUCCESSFULLY IS GOING TO HAVE ADDITIONAL

PSYCHOLOGICAL EFFECTS ON THE USE OF CONTRACEPTIVE METHODS AS WELL AS ALLEVIATING THE QUITE HUMAN PROBLEM OF THE COUPLE WHO WISH TO AND CANNOT HAVE CHILDREN.

I WOULD LIKE NOW TO ADDRESS MYSELF TO A MAJOR GROUP OF DISEASES WHICH CAUSE AN ENORMOUS MORTALITY, PARTICULARLY IN THE WESTERN WORLD. I AM SPEAKING OF DIABETES MELLITUS, OF LIPID ABNORMALITIES AND CONSEQUENT MYOCARDIAL INFARCTION, AND OF OBESITY. IT IS PERHAPS APPROPRIATE TO BEGIN WITH DIABETES SINCE WE ARE NOW IN THE 50TH YEAR OF THE DISCOVERY OF INSULIN, THE DRAMATIC EVENT WHICH CHANGED AN INEVITABLY FATAL DISEASE INTO A TREATABLE, IF NOT CURABLE, DISEASE. I AM SURE YOU DO NOT NEED REMINDING THAT INSULIN IN COMBINATION WITH ORAL HYPOGLYCEMIC AGENTS, WITH DIET AND WITH EVERYTHING ELSE THAT IS CURRENTLY AVAILABLE IS STILL INADEQUATE TO PREVENT COMPLICATIONS OF DIABETES IN A SUBSTANTIAL NUMBER OF INDIVIDUALS AND IS BY NO MEANS THE ANSWER TO THIS PROBLEM. I THINK IT IS UNNECESSARY TO POINT OUT THAT CONSIDERABLE WORK IS REQUIRED BEFORE WE CAN BE SURE OF THE RELATIONSHIPS BETWEEN INSULIN SECRETION, INSULIN SENSITIVITY AND THE DEVELOPMENT OF ATHEROSCLEROTIC CHANGES. UNRAVELING THE CAUSAL RELATIONSHIPS AMONG THESE VARIABLES IS CERTAINLY CRITICAL TO THE DEVELOPMENT OF A REALLY EFFECTIVE METHOD FOR THE THERAPY OF DIABETES.

OBESITY AND LIPID ABNORMALITIES, WHICH SO FREQUENTLY ARE ASSOCIATED WITH ATHEROSCLEROSIS, REPRESENT SOCIETAL PROBLEMS OF THE FIRST MAGNITUDE. IS OBESITY ENDOCRINE? I THINK MOST PEOPLE WOULD DISAGREE WITH THIS HYPOTHESIS BUT IS THERE SOME HYPOTHALAMIC OR CENTRAL NERVOUS SYSTEM MECHANISM WHICH INVOLVES APPETITE REGULATION WHICH IS DISTURBED IN

OBESITY, OR ALTERNATIVELY IS THERE SOME DISTURBANCE IN EARLY CHILDHOOD IN THE NUMBER OF ADIPOSE CELLS SYNTHESIZED? I LEAVE IT TO YOU TO FIND THE ANSWERS TO THESE PROBLEMS, SO THAT WE CAN HAVE SOME RATIONAL AND EFFECTIVE WAY OF TREATING PEOPLE WHO SUFFER FROM GROSS OBESITY. LIPID ABNORMALITIES, I THINK IT IS CLEAR, HAVE SOME ENDOCRINE RELATIONSHIP AS WITNESSED BY THE PROFOUND EFFECT OF THYROID HORMONES ON CHOLESTEROL SYNTHESIS AND EXCRETION, AND AS INTIMATED BY THE MARKED SEX DIFFERENCE IN MYOCARDIAL INFARCTION BETWEEN MEN AND WOMEN. IT SEEMS A REASONABLE HYPOTHESIS THAT THE COMPLETE ELUCIDATION OF THESE HORMONAL EFFECTS WILL PERMIT SOME TYPE OF ENDOCRINE INTERVENTION TO PREVENT THE DEVELOPMENT OF SERIOUS ATHEROSCLEROSIS.

LET ME NOW MENTION ANOTHER PUBLIC HEALTH PROBLEM LESS COMMON AND LESS IMPORTANT IN THE WESTERN WORLD THAN IT WAS FOUR OR FIVE DECADES AGO, BUT CLEARLY AFFECTING TENS OF MILLIONS OF PEOPLE THROUGHOUT THE WORLD, NAMELY ENDEMIC GOITER. I CAN ONLY SALUTE THE IMPORTANT WORK IN DELINEATING THE ROLE OF IODINE IN THE DEVELOPMENT OF GOITER BY KOCHER IN SWITZERLAND AND MARINE IN THE UNITED STATES. I NOTE IN THE PROGRAM OF THE CONGRESS WHAT APPEARS TO BE AN IMPROVEMENT IN THE PROPHYLAXIS OF IODINE DEFICIENT GOITER BY THE USE OF LONG ACTING IODIZED MATERIALS. I WOULD, HOWEVER, DRAW YOUR ATTENTION TO A PROBLEM WHICH SEEMS TO ME LOOMING ON THE HORIZON, PARTICULARLY IN THE WESTERN WORLD WHERE RADIOACTIVE IODINE HAS BEEN SO EXTENSIVELY AND EFFECTIVELY USED TO TREAT HYPERTHYROIDISM. I AM TOLD THAT IN TEN YEARS THERE WILL BE IN THE UNITED STATES ALONE APPROXIMATELY ONE-FOURTH OF A MILLION PEOPLE WHO HAVE BEEN TREATED WITH I^{131} . I AM ALSO TOLD THAT THE

INCIDENCE OF HYPOTHYROIDISM IN THESE INDIVIDUALS TEN TO FIFTEEN YEARS AFTER THERAPY MAY BE AS HIGH AS 50%. IT IS EASILY WITHIN THE CAPABILITIES OF A NON-ENDOCRINOLOGIST TO CALCULATE THAT BETWEEN 100- AND 150,000 PEOPLE WITH HYPOTHYROIDISM IS GOING TO BE A SERIOUS PROBLEM. HOW ARE THESE GOING TO BE RECOGNIZED AND GIVEN APPROPRIATE THERAPY? I DRAW THIS TO YOUR ATTENTION BECAUSE OF THE MAGNITUDE OF THE PROBLEM, AND THE CLEAR RESPONSIBILITY THAT YOU AS ENDOCRINOLOGISTS HAVE TO FACE UP TO IT.

ANOTHER SOCIETAL PROBLEM IS POST-MENOPAUSAL OR ELDERLY OSTEOPOROSIS. I AM INFORMED THAT IN THE UNITED STATES ALONE THERE ARE 4 OR 5 MILLION PEOPLE WITH THIS DISORDER AND IN SPITE OF THE WORK BY MEN SUCH AS FULLER ALBRIGHT SOME YEARS BACK AND ALL THE MORE RECENT WORK ON THOSE HORMONES WHICH GOVERN CALCIUM METABOLISM, WE STILL HAVE NO REALLY EFFECTIVE THERAPY AVAILABLE FOR IT. I DON'T HAVE TO REMIND YOU OF THE BRILLIANT WORK WHICH PRODUCED THE STRUCTURE OF THE PARATHYROID HORMONE, ITS PARTIAL SYNTHESIS, THE ISOLATION AND SEQUENCE OF CALCITONIN AND FINALLY THE DISCOVERY OF THE METABOLIC PATHWAY WHEREBY VITAMIN D IS CONVERTED IN VIVO TO 1,25-DIHYDROCHOLECALCIFEROL, THE METABOLICALLY ACTIVE FORM OF THE VITAMIN. BUT LET ME ASK YOU NOW THAT WE KNOW THE STRUCTURE OF THE TWO POLYPEPTIDE HORMONES WHICH CONTROL CALCIUM LEVELS AND WE KNOW THE STRUCTURE OF THE ACTIVE STEROID WHICH REGULATES CALCIUM INTAKE, WHAT HAVE YOU DONE ABOUT PREVENTING DISORDERS OF CALCIUM METABOLISM OR, INDEED, TREATING THEM EFFECTIVELY? IT SEEMS TO ME THAT THIS IS A MAJOR PUBLIC HEALTH PROBLEM WHICH HAS YET TO BE DEALT WITH IN A PRACTICAL, EFFECTIVE WAY, PARTICULARLY WITH AN AGING POPULATION.

A FINAL SOCIETAL PROBLEM WHICH ENDOCRINOLOGY IT SEEMS TO ME IMPINGES ON IN A WAY WHICH IS NOT ALWAYS CONSIDERED TO BE DIRECT, IS THE PROBLEM OF FOOD SUPPLY, INCLUDING THE USE OF DOMESTICATED ANIMALS FOR FOOD. WHY ENDOCRINOLOGY? IT SEEMS TO ME IT WAS NOT LONG AGO THAT THE USE OF GONADOTROPINS TO PRODUCE TWINNING IN SHEEP WAS PROPOSED AND, INDEED, I GATHER IS STILL USED. THE USE OF ESTROGENS, ABOUT WHICH WE HAVE CONSIDERABLE CONCERN, HAS BEEN EFFECTIVE IN PRODUCING MORE RAPID GROWTH IN CATTLE AS WELL AS IN CHICKENS, AND ARE PROCEDURES ALREADY AVAILABLE IN WHICH ENDOCRINOLOGY HAS HAD SOME EFFECT ON FOOD PRODUCTION. I WOULD, HOWEVER, DIRECT YOUR ATTENTION TO OTHER AND PERHAPS POTENTIALLY MORE IMPORTANT AREAS. WE HAVE AS A CULTURE NOT DOMESTICATED A NEW ANIMAL FOR THE LAST MILLENNIUM. WHAT ARE THE ENDOCRINOLOGIC PROBLEMS IN DOMESTICATING ANIMALS? IS THERE ANYTHING THAT CAN BE DONE TO USE OTHER SPECIES THAN THOSE WHICH HAVE BEEN KNOWN SINCE PREHISTORIC TIMES? HOW ABOUT THE REPRODUCTION OF FISH AND SHELL FISH IN WHAT ARE ESSENTIALLY FARMING MECHANISMS RATHER THAN THE PRIMITIVE HUNTING AND GATHERING METHODS WE NOW USE FOR THE MOST PART IN CATCHING FISH, SHELL FISH, AND CRUSTACEANS? IT SEEMS TO ME THAT ENDOCRINOLOGY BY LOOKING AT SOME OF THESE PROBLEMS FROM A DIFFERENT AND FROM AN IMAGINATIVE VIEWPOINT MAY BE ABLE TO MAKE MAJOR CONTRIBUTIONS TO NEW SOURCES OF FOOD SUPPLY FOR THE PEOPLES OF THE WORLD. ALSO IN CONNECTION WITH FOOD, I WOULD DRAW YOUR ATTENTION TO THE INCREASING WORRY THAT MOST OF US HAVE ABOUT THE USE OF PESTICIDES, PARTICULARLY THOSE THAT ARE PERSISTANT AND HAVE EFFECTS ON HUMAN BEINGS AS WELL AS SERIOUS ECOLOGIC CONSEQUENCES. I DRAW YOUR ATTENTION TO THE SEX ATTRACTANTS, OR PHEROMONES WHICH HAVE

BEEN ISOLATED IN SOME INSTANCES, AND, I GATHER, USED SUCCESSFULLY IN THE CONTROL OF THE ORIENTAL FRUIT FLY IN SOME OF THE MARIANNA ISLANDS AND THE GYPSY MOTH IN OTHER AREAS. IT SEEMS TO ME THAT THIS IS A POTENTIALLY VERY EXCITING RESEARCH. I CONGRATULATE YOU ON YOUR PAST WORK AND ENCOURAGE YOU TO CONTINUE.

NOW I WOULD LIKE TO COMMENT RATHER BRIEFLY ON THE MORE BASIC ASPECTS OF ENDOCRINE RESEARCH INVOLVED IN GROWTH, IN DIFFERENTIATION AND IN THE MECHANISM OF HORMONE ACTION. I DRAW YOUR ATTENTION TO THE WORK OF SUTHERLAND AND RALL ON THE ROLE OF CYCLIC ADENOSINE MONOPHOSPHATE AS A SECOND MESSENGER IN HORMONE ACTION AND THE MORE RECENT WORK SHOWING ITS PROFOUND EFFECT IN BACTERIAL METABOLISM. WHEN I HEAR REPORTS IN OUR OWN LABORATORIES OF PEOPLE WORKING ON REGULATION OF TRANSCRIPTION BY CYCLIC AMP, WHEN I HEAR TALK OF HORMONE RECEPTORS, WHEN I HEAR TALK OF EFFECTS ON TRANSLATION, ON RIBOSOME SYNTHESIS, I BECOME SOMEWHAT CONFUSED AS TO WHETHER I AM LISTENING TO AN ENDOCRINOLOGIST, A MOLECULAR BIOLOGIST, A VIROLOGIST OR A BACTERIAL GENETICIST. IT SEEMS TO ME THAT THIS IS A HEALTHY STATE OF AFFAIRS IN THAT SCIENTISTS INVESTIGATING AT THE MOST FUNDAMENTAL LEVEL POSSIBLE MAY APPROACH BASIC BIOLOGICAL PROCESSES THROUGH A VARIETY OF DOORS, AND I HAVE A STRONG SUSPICION THAT AN APPROACH THROUGH THE DOOR OF ENDOCRINOLOGY MAY WELL LEAD TO KNOWLEDGE THAT HAS WIDE APPLICATION IN AREAS AS DIVERSE AS GENETIC DISEASES, CANCER AND AGING. I CONGRATULATE YOU ON THIS FUNDAMENTAL WORK AND ENCOURAGE YOU, WITH OTHER BIOMEDICAL SPECIALISTS, TO WREST FROM NATURE THE MOST RECONDITE MYSTERIES OF CELL GROWTH, METABOLISM AND DIVISION. WE MAY THEN BE ABLE TO SOLVE SOME OF THE PROBLEMS WHICH HAVE FACED MANKIND SINCE ITS BEGINNING AND WHICH ASSUME SUCH URGENCY IN OUR SOCIETY TODAY.

FINALLY, AS I SEE THE ROSTER OF PARTICIPANTS AT THIS CONGRESS WHO REPRESENT SO MANY NATIONS, I FEEL I MUST SAY A WORD ABOUT INTERNATIONAL COOPERATION AS IT PERTAINS TO HEALTH AND BIOMEDICAL RESEARCH.

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET
OF THE NATIONAL INSTITUTES OF HEALTH ¹

Robert Q. Marston, M.D.²

	<u>Page</u>
I. Organization of the National Institutes of Health	1
II. The Current Year (Fiscal Year 1972) Budget	3
III. The President's 1973 Budget	6
IV. Status of NIH Appropriation 1973	9
V. Federal Budgets for Medical R&D, FY 1970-73	10
VI. Legislation and Pending Bills	11

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Marine Biological Laboratory, Woods Hole, Massachusetts, July 25, 1972.

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Education, and Welfare

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

SECRETARY, DHEW

ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS

FDA

NIN

HSMHA

NATIONAL INSTITUTES

BUREAU OF HEALTH MANPOWER EDUCATION

ALLERGY & INFECTIOUS DISEASES

ARTHRITIS & METABOLIC DISEASES

CANCER

NATIONAL LIBRARY OF MEDICINE

ALLIED HEALTH MANPOWER

DENTAL HEALTH

CHILD HEALTH & HUMAN DEVELOPMENT

DENTAL RESEARCH

ENVIRONMENTAL HEALTH SCIENCES

NATIONAL MEDICAL AUDIOVISUAL CENTER

EXTRAMURAL PROGRAMS

MANPOWER INTELLIGENCE

NURSING

EYE

GENERAL MEDICAL SCIENCES

HEART & LUNG

LIBRARY OPERATIONS

LISTER HILL NATIONAL CENTER FOR MEDICAL LIBRARY SERVICES

PHYSICIAN & HEALTH PROFESSIONALS EDUCATION

NEUROLOGICAL DISEASES & STROKE

SPECIALIZED INFORMATION SERVICES

RESEARCH & SERVICE DIVISIONS

BIOLOGICS STANDARDS

CLINICAL CENTER

COMPUTER RESEARCH & TECHNOLOGY

FOGARTY INTER NATIONAL CENTER

RESEARCH GRANTS

RESEARCH RESOURCES

RESEARCH SERVICES

Principal Officers, National Institutes of Health:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Leon M. Schwartz
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Thomas Malone
Associate Director for Collaborative Research	Dr. Leon Jacobs

II. THE CURRENT YEAR (FISCAL 1972) BUDGET

A. General Background

The 1972 President's Budget request for the NIH amounted to \$1.9 billion--including \$100 million to launch the Cancer Conquest Program--against which appropriations were enacted in two phases.

The first phase, in the amount of \$1.7 billion, was approved August 10, 1971. This contained \$184.6 million for elements of the Bureau of Health Manpower Education (BHME) for which there was authorizing legislation, and \$1.5 billion for all other NIH activities, including a Congressional increase of \$119 million for research.

The second phase contained a supplemental appropriation of \$492.9 million for BHME programs authorized by Public Laws 92-157 and 92-158, dated November 18, 1971.

Total 1972 appropriations exceeded \$2.1 billion. Pending the development of a "1972 spending plan," virtually all increases over the President's Budget were placed in an "administrative reserve." However, all funds have been released except for some BHME construction grant funds which will be carried over for obligation in fiscal year 1973.

The following table shows a comparison of 1971 budget authority with that of 1972. The amounts deviate slightly from the actual appropriation since they have been made comparable to the 1973 estimate, which will be discussed later.

1972 BUDGET AUTHORITY
(in thousands of dollars)

<u>Activity</u>	<u>1971</u>	<u>1972</u>	<u>Increase over 1971</u>
<u>Research Institutes & Divisions</u>			
Research grants.....	767,043	\$ 791,573	\$124,530
Training grants and fellowships...	81,650	182,406	756
Laboratory and clinical research..	104,350	113,846	9,496
Research & development contracts..	156,731	232,181	75,450
Collaborative research and support	31,028	39,147	8,119
Other direct operations.....	48,747	59,106	10,359
Construction (Cancer).....		16,000	16,000
Subtotal, IRD's.....	<u>1,189,549</u>	<u>1,434,259</u>	<u>244,710</u>
<u>Bureau of Health Manpower Education</u>			
Medical, dental and related health professions.....	300,473	457,926	157,453
Nursing.....	74,421	144,390	69,969
Public health.....	18,495	18,999	504
Allied health.....	19,496	30,614	11,118
Program direction and manpower analysis.....	4,941	9,712	4,771
Other.....	14,097	15,850	1,753
Subtotal, BHME.....	<u>431,923</u>	<u>677,491</u> ^{1/}	<u>245,568</u>
<u>National Library of Medicine.....</u>	<u>21,510</u>	<u>24,086</u>	<u>2,576</u>
<u>Other.....</u>	<u>10,498</u>	<u>14,619</u>	<u>4,121</u>
TOTAL, NIH.....	<u>\$1,653,480</u> ^{2/}	<u>\$2,150,455</u> ^{2/}	<u>\$496,975</u>

1/ Total funds available for obligation are estimated at \$777.7 million, including \$96.7 million for advance obligational authority, plus other carryover funds appropriated prior to 1972.

2/ Includes Cancer Research Initiative of \$232,969,000 in 1971 and \$337,622,000 in 1972. Excludes Scientific Activities Overseas funds of \$28,944,000 in 1971 and \$25,545,000 in 1972.

B. Explanation

1. The approved 1972 budget contained a number of significant features as followed:

a. Research--an increase over fiscal year 1971 of \$244.7 million or approximately 21 percent. Major emphasis was placed on launching the cancer research initiative; expanding activities concerned with heart and lung diseases, including sickle cell anemia; developing plans for establishing spinal cord injury centers and for expanding research on stroke; and expanding research in other special initiative areas, including family planning, environmental health sciences, and dental caries.

b. Health manpower education--an increase over fiscal year 1971 of \$245.6 million, designed to increase significantly the future supply of health manpower and to develop new types of personnel and modes of practice to make competent health care more readily and uniformly available. Major activities increased are institutional support, student assistance, and construction.

c. National Library of Medicine--an increase over fiscal year 1971 of \$2.6 million, designed to enhance overall activities of the Library.

III. THE PRESIDENT'S 1973 BUDGET

Activity	(In thousands)		
	1972 Column Comparable	1973 Estimate	Change
<u>Research Institutes & Divisions</u>			
Research grants.....	\$ 791,573	\$ 852,837	\$ +61,264
Training grants and fellowships.....	182,406	186,363	+3,957
Laboratory and clinical res.....	113,846	117,360	+3,514
Research and development contracts..	232,121	263,209	+31,028
Collaborative res. and support.....	39,147	41,653	+2,506
Other direct operations.....	59,106	62,790	+3,684
Construction (cancer).....	16,000	49,000	+33,000
Subtotal, IRD's.....	1,434,259	1,573,212	+138,953
<u>Bureau of Health Manpower Education</u>			
Medical, dental and related health professions.....	457,926	331,433	-126,493
Nursing.....	144,390	122,783	-21,607
Public health.....	18,999	21,549	+2,550
Allied health.....	30,614	35,560	+4,946
Program direction & manpower anal...	9,712	8,630	-1,082
Other.....	15,850	16,700	+ 850
Subtotal, BHME.....	677,491	536,655	-140,836
<u>National Library of Medicine.....</u>	24,086	28,104	+4,018
<u>Other.....</u>	14,619	20,026	+5,407
Total, NIH.....	\$ <u>2,150,455</u> ^{1/}	\$ <u>2,157,997</u> ^{1/}	\$ <u>+7,542</u>

1/ Includes Cancer Research Initiative of \$337,622,000 in 1972 and \$430,000,000 in 1973. Excludes Scientific Activities Overseas of \$25,545,000 in 1972 and \$25,619,000 in 1973.

Highlights of the 1973 Budget

The President's 1973 budget for NIH provides an overall net increase of \$7.5 million. This apparently slight increase is the result of a requested decrease for BHME's programs due to a carryover of 1972 construction funds for obligation in fiscal year 1973. When viewed on an obligational basis, the decrease for BHME is \$11 million and the net increase in obligations for total NIH is \$135.4 million.

1. Research: The requested net increase over 1972 is \$138.9 million or approximately 10 percent. The major features of the budget for research are:

a. An increase of \$92 million in cancer research for continuation and expansion of the cancer research initiative, including the National Cancer Plan and construction of new centers and upgrading of present facilities;

b. An increase of \$22 million in heart and lung research, including such special areas as sickle cell disease, pulmonary diseases, arteriosclerosis and medical devices development;

c. An increase of \$5 million for expanded research in arthritis, kidney disease, diabetes and digestive diseases;

d. An increase of \$10 million directed at such activities as population research, mental retardation, sudden infant death syndrome and nutrition;

e. Except for the cancer initiative, no major change is being sought for research fellowships and training grants until studies underway reveal what the future course should be for these activities.

2. Health Manpower Education: The net decrease of \$140.8 million was requested based on the fact that no new construction grant funds were required because of the large appropriation in 1972 that allows for a sizeable carryover for use in 1973. Excluding construction, major features of the request are:

a. An increase of \$12.6 million for institutional support for medical, dental and related health professional schools including allied health and public health schools. The increase should help put the schools on firmer financial footing and the incentives for expanding enrollment and shortening curriculum should have the effect of producing more trained health personnel more rapidly;

b. An increase of \$5.9 million for student assistance to medical and dental students designed to provide support to a greater number of students and to provide support for the more flexible forgiveness and cancellation clauses contained in the Comprehensive Health Manpower Training Act of 1971.

3. National Library of Medicine: The requested increase over 1972 of \$4 million will provide two major features:

a. An increase of \$1.6 million for assistance grants to other medical libraries;

b. An increase of \$1.2 million for the Lister Hill Center which is dedicated to bringing modern communication technology into the service of practitioners and assisting to improve the medical services available in remote areas.

4. Summary: The following table is a summary by appropriation for the past, present and future years:

SUMMARY BY APPROPRIATION

	1971 <u>Comp.</u>	1972 <u>Comp.</u>	1973 <u>Estimate</u>	<u>Change</u>
<u>Research Institutes & Divisions</u>				
Bio Standards.....	\$ 8,725	\$ 9,205	\$ 9,297	\$ +92
Cancer.....	232,969	337,622	430,000	+92,378
Heart.....	195,739	232,168	254,416	+22,248
Dental.....	35,704	43,404	44,076	+672
Arthritis.....	138,011	153,152	158,394	+5,242
Neuro.....	102,318	116,581	117,298	+717
Allergy.....	99,803	108,749	111,907	+3,158
Gen. Med. Sci.....	159,886	173,513	175,716	+2,203
Child Health.....	94,816	116,916	126,696	+9,780
Eye.....	31,178	37,255	37,201	-54
Environmental Health.....	20,237	26,408	28,817	+2,409
Research Resources.....	66,431	74,948	74,929	-19
Fogarty Inter. Center....	3,732	4,338	4,465	+127
Total, IRD's.....	\$1,189,549	\$1,434,259	\$1,573,212	\$+138,953
<u>Bureau of Health Manpower Educ.</u>				
	431,923	677,491	536,655	-140,836
<u>National Library of Medicine</u>				
	21,510	24,086	28,104	+4,018
<u>Office of the Director</u>				
	10,498	11,054	11,526	+472
<u>Buildings & Facilities</u>				
	---	3,565	8,500	+4,935
Total, NIH	\$1,653,480 ^{1/}	\$2,150,455 ^{1/}	\$2,157,997 ^{1/}	\$ +7,532

^{1/} Excludes amounts for the appropriation, "Scientific Activities Overseas" (SAO) which is shown with NIH for presentation purposes in the President's Budget. SAO is administered by the Office of International Health, DHEW.

IV. STATUS OF NIH APPROPRIATION 1973

Summary by Appropriation
(in thousands)

	1973 President's Budget	1973 House Allowance	1973 Senate Allowance
Research Institutes & Divisions:			
Biologic Standards.....	\$ 9,297	\$ 9,528	9,528
Cancer.....	430,000	492,205	492,205
Heart.....	254,416	300,000	350,000
Dental.....	44,076	46,991	54,000
Arthritis.....	158,394	167,316	182,000
Neurology.....	117,298	130,672	145,000
Allergy.....	111,907	113,414	135,000
General medical sciences.....	175,716	183,171	206,000
Child Health.....	126,696	130,429	160,000
Eye.....	37,201	38,562	45,000
Environmental health.....	28,817	30,956	32,000
Research resources.....	74,929	75,073	83,000
Fogarty International Center.....	4,465	4,666	6,000
Total IRD's.....	1,573,212	1,722,983	1,899,733
<u>Bureau of Health Manpower Education</u>	536,655	742,628	931,178
<u>National Library of Medicine.....</u>	28,104	28,568	29,068
<u>Office of the Director.....</u>	11,526	12,042	13,042
<u>Buildings and Facilities.....</u>	8,500	8,500	33,480
TOTAL, NIH.....	<u>\$ 2,157,997</u>	<u>\$ 2,514,721</u>	<u>\$ 2,906,501</u>

V. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1973
(in millions)*

Agency	<u>1970</u> actual	<u>1971</u> actual	<u>1972</u> est.	<u>1973</u> obligations	<u>Increase</u> 1973/72	<u>%</u> inc.
Total Fed.	<u>\$1,664</u>	<u>\$1,857</u>	<u>\$2,162</u>	<u>\$2,370</u>	<u>\$208</u>	<u>10</u>
Agriculture	50	60	65	72	7	11
AEC	104	105	107	115	8	7
DoD	125	124	124	137	13	10
Environ. Protection	-	13	17	20	3	18
DHEW**	1,177	1,298	1,568	1,706	138	9
(NIH)	(873)	(1,039)	(1,266)	(1,369)	(103)	(8)
NASA	86	75	60	58	-2	-3
NSF	28	34	35	35	0	0
VA	59	63	68	75	7	10
Other	35	85	118	152	34	29

*Covers support of medical and health-related R&D (projects, resources, and general support including P.L. 480 funding for research) but not training or construction.

**FY 1970 includes those research programs transferred to the Environmental Protection Agency in December 1970.

VI. LEGISLATION AND PENDING BILLS

<u>BILL</u>	<u>SENATE</u>	<u>HOUSE</u>	<u>FINAL</u>
National Institute of Gerontology (S. 887, H.R. 14424)	(OR) 6/21/72	(P) 7/18/72	
National Heart, Blood Vessel, Lung, and Blood Act (S.3323, H.R. 15801)	(P)	(P) 7/18/72	
Multiple Sclerosis (H.R. 15475)		(R) 6/27/72	
Cooley's Anemia (H.R. 15474)		(R) 6/27/72	
Appropriations for Labor/DHEW-1973 (H.R. 15417)	(P) 6/27/72	(P) 6/15/72	
Consumer Product Safety Act (S. 3419, H.R. 15003)	(P) 6/21/72	(R) 6/20/72	
VA Medical Schools (Manpower) (S. 2219, H.J. Res. 748)	(P) 4/27/72	(P) 7/19/71	
Health Facilities, Health Manpower, & Community Mental Health Centers Act (S. 3716) (Allied Health)	(OR) 6/21/72		
Medical Emergency Transportation & Medical Services Acts (S. 3221, H.P. 12563, H.R. 12787)		H.R. 15859 (clean bill) (AF) 6/27/72	
Children's Dental Health (S. 1874, H.R. 10356)	(P) 12/10/71		
Military Medical Schools (Manpower) (H.R. 2)	(P) 6/06/72	(P) 11/03/71	
Department of Human Resources (S. 1432, H.R. 6961, H.R. 6966)	(HB) 5/25/71	(HB) 6/02/71	
Advisory Committees (S. 3529, H.R. 4383)	(AF) 4/12/72	(P) 5/09/72	
Health Maintenance Organizations (S. 3327, H.R. 5615, H.R. 5766)	(OR) 6/21/72	(HC) 5/18/72	
D.C. Medical Schools (H.R. 13713)		(AF) 4/20/72	
Health Science & Society Commission (S.J. Res. 75)	(P) 12/02/71		
Welfare/Social Security (H.R. 1)	(HC) 2/09/72	(P) 6/22/71	

Key: AF - Approved by Subcommittee
for Full Committee
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CA - Conference Agreement Reached
CS - Conference Scheduled
DB - Debate Begun
HB - Hearings Begun

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NA - No Action Required
OR - Ordered Reported
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R - Reported

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- 1) P.L. 92-48
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July 9, 1971
- 2) P.L. 92-52
HPEA Student Loan and Scholarship Extension
July 9, 1971
- 3) P.L. 92-69
Medical Information Exchange Extension
August 6, 1971
- 4) P.L. 92-80
Labor/DHEW Appropriations for Fiscal 1972
August 10, 1971
- 5) P.L. 92-86
National Science Foundation Authorization Act of 1972
August 11, 1971
- 6) P.L. 92-157
Comprehensive Health Manpower Training Act of 1971
November 18, 1971
- 7) P.L. 92-158
Nurse Training Act of 1971
November 18, 1971
- 8) P.L. 92-218
National Cancer Act of 1971
December 23, 1971
- 9) P.L. 92-255
Drug Abuse Office and Treatment Act of 1972
March 21, 1972
- 10) P.L. 92-258
Nutrition Program for Older Americans
March 22, 1972
- 11) P.L. 92-294
National Sickle Cell Anemia Control Act
May 16, 1972
- 12) P.L. 92-303
Black Lung Benefits Act of 1972
May 19, 1972

- 13) P.L. 92-305
National Institute of Arthritis, Metabolism, and Digestive Diseases
May 19, 1972
- 14) P.L. 92-306
Supplemental Appropriations Act, 1972 (Cancer)
May 27, 1972

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET
OF THE NATIONAL INSTITUTES OF HEALTH ¹

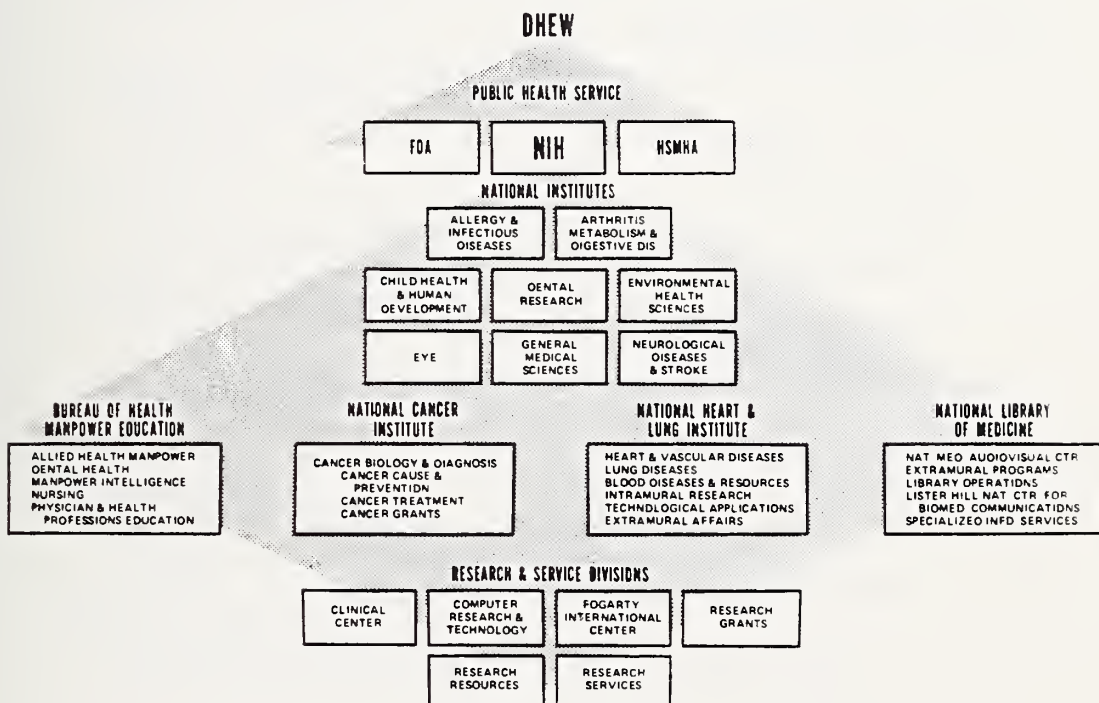
Robert Q. Marston, M.D.²

	<u>Page</u>
I. Organization of the National Institutes of Health	1
II. The Current Year (Fiscal 1973) Budget	3
III. 1973 Budget Authority	4
IV. Status of NIH Appropriation 1973	7
V. Federal Budgets for Medical R&D, FY 1970-73	8
VI. Legislation and Pending Bills	9

¹ Prepared for Annual Meeting of the Association for Academic Health Centers, San Juan, Puerto Rico, October 14, 1972.

² Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



Principal Officers, National Institutes of Health:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Leon M. Schwartz
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Thomas Malone
Associate Director for Collaborative Research	Dr. Leon Jacobs

II. THE CURRENT YEAR (FISCAL 1973) BUDGET

A. General Background

The 1973 President's Budget request for the NIH amounted to \$2.2 billion, including an increase of \$53.3 million for the National Cancer Institute.

Both Houses of the Congress have acted on the DHEW Appropriations Bill, but as of October 6, 1972 no Conference action had taken place. Briefly, the House allowed \$2.5 billion, or an increase of nearly \$330 million. The increase would permit the support of research grants, training grants and fellowships at close to the 1972 program level and provide increased support for Health Manpower construction, institutional support and student assistance. The Senate passed the vetoed Bill with the proviso that total DHEW appropriations can be reduced to the level of the House Bill, except that no appropriation or activity can be reduced more than 10% below the vetoed Bill. No accurate figures by appropriation are available at this time (October 6, 1972).

The following tables show a comparison of 1972 Budget Authority with the 1973 President's Budget. The amounts for 1972 deviate slightly from the actual appropriation since they have been made comparable to the 1973 estimate.

III. 1973 BUDGET AUTHORITY (in thousands of dollars)

<u>Activity</u>	<u>1972</u>	<u>1973 Estimate</u>	<u>Change over 1972</u>
<u>Research Institutes & Divisions:</u>			
Research grants.....	\$791,573	\$852,837	+\$61,264
Training grants and fellowships.....	186,406	186,363	-43
Laboratory and clinical research....	114,945	121,160	+6,215
Research and development contracts..	232,181	263,054	+30,873
Collaborative research and support..	39,768	43,161	+3,393
Other direct operations.....	59,461	64,623	+5,162
Construction (Cancer).....	52,000	49,000	-3,000
Subtotal, Institutes & Divisions..	<u>1,476,334</u>	<u>1,580,198</u>	<u>+103,864</u>
<u>Bureau of Health Manpower Education:</u>			
Medical, dental and related health professions.....	469,795	344,560	-125,235
Nursing.....	144,399	122,934	-21,465
Public health.....	18,999	21,571	+2,572
Allied health.....	30,620	35,665	+5,045
Program direction and manpower analysis.....	9,749	8,898	-851
Other.....	<u>4,000</u>	<u>4,000</u>	<u>---</u>
Subtotal, BHME.....	<u>677,562</u>	<u>537,628</u> ^{1/}	<u>-139,934</u>
<u>National Library of Medicine.....</u>	<u>24,127</u>	<u>28,568</u>	<u>+4,441</u>
<u>Other.....</u>	<u>14,889</u>	<u>20,542</u>	<u>+5,653</u>
TOTAL, NIH.....	<u>2,192,912</u> ^{2/}	<u>2,166,936</u> ^{2/}	<u>-25,976</u>

^{1/} Total funds available for obligation are estimated at \$608.0 million, including \$70.4 million for advance obligational authority, plus other carryover funds appropriated prior to 1973.

^{2/} Includes Cancer Research Initiative of \$378,885,000 in 1972 and \$432,205,000 in 1973. Excludes Scientific Activities Overseas funds of \$25,545,000 in 1972 and \$25,619,000 in 1973.

Highlights of the 1973 Budget

The President's 1973 budget for NIH provides an overall net decrease of \$26.0 million. This is the result of a requested decrease for BHME's programs due to a carryover of 1972 construction funds for obligation in fiscal year 1973. When viewed on an obligational basis, the decrease for BHME is \$11 million and the net increase in obligations for total NIH is \$135.4 million.

1. Research: The requested net increase over 1972 is \$103.9 million or approximately 7 percent. The major features of the budget for research are:

- a. An increase of \$53 million in cancer research for continuation and expansion of the cancer research initiative, including the National Cancer Plan and construction of new centers and upgrading of present facilities;
- b. An increase of \$22 million in heart and lung research, including such special areas as sickle cell disease, pulmonary diseases, arteriosclerosis and medical devices development;
- c. An increase of \$6 million for expanded research in arthritis, kidney disease, diabetes and digestive diseases;
- d. An increase of \$11 million directed at such activities as population research, mental retardation, sudden infant death syndrome and nutrition;
- e. Except for the cancer initiative, no major change is being sought for research fellowships and training grants until studies underway reveal what the future course should be for these activities.

2. Health Manpower Education: The net decrease of \$139.9 million was requested based on the fact that no new construction grant funds were required because of the large appropriation in 1972 that allows for a sizeable carryover for use in 1973. Excluding construction, major features of the request are:

- a. An increase of \$8.6 million for institutional support for medical, dental and related health professional schools including allied health and public health schools. The increase should help put the schools on firmer financial footing and the incentives for expanding enrollment and shortening curriculum should have the effect of producing more trained health personnel more rapidly;
- b. An increase of \$5.9 million for student assistance to medical and dental students designed to provide support to a greater number of students and to provide support for the more flexible forgiveness and cancellation clauses contained in the Comprehensive Health Manpower Training Act of 1971.

3. National Library of Medicine: The requested increase over 1972 of \$4 million will provide two major features:

- a. An increase of \$1.6 million for assistance grants to other medical libraries;
- b. An increase of \$1.2 million for the Lister Hill Center which is dedicated to bringing modern communication technology into the service of practitioners and assisting to improve the medical services available in remote areas.

4. Summary: The following table is a summary by appropriation for the past, present and future years:

SUMMARY BY APPROPRIATION
(In thousands)

	1971 <u>Comp.</u>	1972 <u>Comp.</u>	1973 <u>Estimate</u>	<u>Change</u>
<u>Research Institutes & Div.:</u>				
Biologics standards.....	\$8,725	\$9,294	\$9,528	+\$234
Cancer.....	232,969	378,885	432,205	+53,320
Heart.....	195,739	232,688	255,280	+22,592
Dental.....	35,704	43,404	44,415	+1,011
Arthritis.....	138,011	153,325	159,089	+5,764
Neurology.....	102,318	116,722	117,877	+1,155
Allergy.....	99,803	109,156	112,649	+3,493
General medical sciences.	159,886	173,472	175,960	+2,488
Child health.....	94,816	116,510	127,244	+10,734
Eye.....	31,178	37,132	37,384	+252
Environmental health....	20,237	26,408	29,013	+2,605
Research resources.....	66,431	74,981	75,009	+28
Fogarty Internat'l Center	3,732	4,357	4,545	+188
Total, Institutes & Div.	1,189,549	1,476,334	1,580,198	+103,864
<u>Bureau of Health Manpower</u>				
Education.....	435,006	677,562	537,628	-139,934
<u>Nat'l Library of Medicine..</u>	21,510	24,127	28,568	+4,441
<u>Office of the Director.....</u>	10,498	11,324	12,042	+718
<u>Buildings and Facilities...</u>	--	3,565	8,500	+4,935
Total, NIH..	<u>1,656,563^{1/}</u>	<u>2,192,912^{1/}</u>	<u>2,166,936^{1/}</u>	<u>-25,976</u>

^{1/} Excludes amounts for the appropriation, "Scientific Activities Overseas" (SAO) which is shown with NIH for presentation purposes in the President's Budget. SAO is administered by the Office of International Health, DHEW.

IV. STATUS OF NIH APPROPRIATION-1973

Summary by Appropriation
(In thousands)

	1973 President's Budget	1973 New House Allowance	1973 Senate Allowance ^{1/}
<u>Research Institutes & Divisions:</u>			
Biologics standards.....	\$9,528	\$9,528	\$9,528
Cancer.....	432,205	484,705	492,205
Heart.....	255,280	294,410	320,000
Dental.....	44,415	46,669	49,795
Arthritis.....	159,089	166,288	173,190
Neurology.....	117,877	129,073	136,403
Allergy.....	112,649	113,318	122,048
General medical sciences.....	175,960	182,270	192,302
Child health.....	127,244	130,031	142,257
Eye.....	37,384	38,415	41,137
Environmental health.....	29,013	30,713	31,374
Research resources.....	75,009	75,065	78,244
Fogarty International Center...	4,545	4,651	5,200
Total, Institutes & Divisions	1,580,198	1,705,136	1,793,683
<u>Bureau of Health Manpower</u>			
Education.....	537,628	717,003	850,428
<u>National Library of Medicine.....</u>	28,568	28,568	28,818
<u>Office of the Director.....</u>	12,042	12,042	12,542
<u>Buildings and Facilities.....</u>	8,500	8,500	12,580
TOTAL, NIH.....	<u>2,166,936</u>	<u>2,471,249</u>	<u>2,698,051</u>

^{1/} The Senate version provides that the President may reduce the DHEW appropriation to the amount provided in the House bill, but that no appropriation or activity may be reduced by more than 10% from the level of the vetoed bill.

V. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1973

(in millions)*

Agency	<u>1970</u> <u>actual</u>	<u>1971</u> <u>actual</u>	<u>1972</u> <u>est. obligations</u>	<u>1973</u> <u>obligations</u>	<u>Increase</u> <u>1973/72</u>	<u>%</u> <u>inc.</u>
Total Fed.	<u>\$1,664</u>	<u>\$1,857</u>	<u>\$2,162</u>	<u>\$2,370</u>	<u>\$208</u>	<u>10</u>
Agriculture	50	60	65	72	7	11
AEC	104	105	107	115	8	7
DoD	125	124	124	137	13	10
Environ. Protection	-	13	17	20	3	18
DHEW** (NIH)	1,177 (873)	1,298 (1,039)	1,568 (1,266)	1,706 (1,369)	138 (103)	9 (8)
NASA	86	75	60	58	-2	-3
NSF	28	34	35	35	0	0
VA	59	63	68	75	7	10
Other	35	85	118	152	34	29

*Covers support of medical and health-related R&D (projects, resources, and general support including P.L. 480 funding for research) but not training or construction.

**FY 1970 includes those research programs transferred to the Environmental Protection Agency in December 1970.

VI. LEGISLATION AND PENDING BILLS

<u>BILL</u>	<u>SENATE</u>	<u>HOUSE</u>	<u>FINAL</u>
National Institute of Gerontology (S. 887, H.R. 14424)	(P) 9/21/72	(P) 7/18/72	
Multiple Sclerosis (H.R. 15475, S. 3659)	(P) 9/26/72	(P) 8/1/72	
Appropriations for Labor/DHEW, 1973 (H.R. 15417)	(P) 6/27/72	(P) 6/15/72	Vetoed
Appropriations for Labor/DHEW, 1973 (H.R. 16654)	(P) 10/3/72	(P) 9/19/72	
Consumer Product Safety Act (S. 3419, H.R. 15003)	(P) 6/21/72 (C) 10/3/72	(P) 9/20/72 (C) 10/3/72	
VA Medical Schools (Manpower) (S. 2219, H.J. Res. 748)	(P) 4/27/72	(P) 7/19/71	
Health Facilities, Health Manpower, & Community Mental Health Centers Act (S. 3716) (Allied Health)	amended (P) 9/20/72		
Medical Emergency Transportation & Medical Services Acts (S. 3221, H.R. 12563, H.R. 12787)		H.R. 15859 (clean bill) (P) 10/2/72	
Children's Dental Health (S. 1874, H.R. 10356)	(P) 12/10/71		
Department of Human Resources (S. 1432, H.R. 6961, H.R. 6966)	(HB) 5/25/71	(HB) 6/02/71	
Advisory Committees (S. 3529, H.R. 4383)	(P) 9/12/72	(P) 5/09/72	Signed 10/6/72
Health Maintenance Organizations (S. 3327, H.R. 5615, H.R. 5766)	(P) 9/20/72	H.R. 16782 (clean bill) (AF) 9/19/72	
D.C. Medical Schools (H.R. 13713)		(AF) 4/20/72	
Health Science and Society Commission (S.J. Res. 75)	(P) 12/2/71		
Welfare/Social Security (H.R. 1)	(P) 10/5/72	(P) 6/22/71	
Public Health Personnel Trainee- ship Program Extension (S. 3441)	(P) 8/16/72		
Medical Libraries Assistance Extension (S. 3752, H.R. 16933)	(P) 8/16/72		
Emergency Medical Personnel Act Amendments (S. 3858, H.R. 16755)	(P) 8/13/72	(OR) 10/4/72	

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- 7) P.L. 92-158
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- 10) P.L. 92-258
Nutrition Program for Older Americans
March 22, 1972
- 11) P.L. 92-294
National Sickle Cell Anemia Control Act
May 16, 1972
- 12) P.L. 92-303
Black Lung Benefits Act of 1972
May 19, 1972

- 13) P.L. 92-305
National Institute of Arthritis, Metabolism, and Digestive Diseases
May 19, 1972
- 14) P.L. 92-306
Supplemental Appropriations Act, 1972 (Cancer)
May 27, 1972
- 15) P.L. 92-414
Cooley's Anemia
August 29, 1972
- 16) P.L. 92-423
National Heart, Blood Vessel, Lung, and Blood Act
September 19, 1972
- 17) P.L. 92-426
Uniformed Services Health Professions Revitalization Act of 1972
September 21, 1972

REFLECTIONS ON SCIENCE AND MEDICINE*

Robert O. Marston, M.D.
Director
National Institutes of Health
Bethesda, Maryland

No other institution demonstrates quite so clearly the basic polar tugs of our society as does the university--and within the university--the Medical School.

On the one hand are the crises of today; on the other, the need to invest in tomorrow--on the one side, the importance of the elite--the other, egalitarianism.

Almost a decade ago I was a member of a site visit team which was impressed favorably with your decision to become a medical school without compromising--indeed, as another part of your historic commitment to the immediate health of the people of your community.

Reason enough for me to be pleased to be here for your first academic convocation! In addition, at a particularly critical time in my own career I had the good fortune to have a very close working relationship with George James who was the Chairman of the initial review committee during the early

*To be presented at the Academic Convocation, Mount Sinai School of Medicine, New York City, New York, October 27, 1972.

days of the Regional Medical Programs. In that capacity he was one of a handful of major outsider advisers that I became increasingly dependent on. This was the same time that Dr. James was deeply involved in the development of the medical school here and through his enthusiastic eyes I had an opportunity to see the promise, excitement and dedication which went into the creation of the expanded missions of this institution.

I want to share with you some reflections on science and medicine from the perspective of a Federal official who during the past half dozen years has served at the national level across the spectrum of biomedical research, education in the health area, and at an earlier stage in the Federal programs related to the organization and delivery of health services.

A writer seeking headlines might summarize what I intend to say as follows: Marston cautioned against overemphasis on targeted programs in biomedical research, against excesses of the new consumerism, and he worried that too much money might corrupt the medics.

I have indeed chosen to speak on those matters but my most important message is that professionals in medicine, by virtue of specialized and intensive training, have a unique opportunity to contribute to the well-being of society.

Let me turn now to speak first, about the usefulness of science in the medical field--what things it can do and what things it cannot do; secondly, to talk about the new consumerism--its strengths and some of its weaknesses; and third, to focus on the hopes and fears of the American people--specifically in matters of health.

Science and Medicine

The discovery of the power of the experimental approach may indeed prove to be the dominant feature of the 20th Century. The experimental approach is the most powerful instrument for seeking the truth. Former Chief Justice, Charles E. Hughes stated it very well at the American Association for the Advancement of Science Annual Meeting in 1925:

"If to an increasing degree we have the security of sound public opinion, if the extravagances and diatribes of political appeal fail of their object, and if, notwithstanding the apparent confusion and welter of our life, we are able to find a steadiness of purpose and a quiet dominating intelligence, it is largely because of the multitude of our people who have been trained to a considerable extent in the scientific method, who look for

facts, who have cultivated the habit of inquiry and in a thousand callings face the tests of definite investigations. With scientific applications on every hand, the American people are daily winning their escape from the danger of being fooled...We need your interest in knowledge for its own sake; the self-sacrificing ardor of your leaders; your ceaseless search for truth; your distrust of phrases and catch-words; your rejection of every plausible counterfeit; your willingness to discard every disproved theory however honored by tradition, while you jealously conserve every gain of the past against madcap assault; your quiet temper, and, above all, your faith in humanity and your zeal to promote the social welfare. We need your horizon, your outlook on the world."

But on the other side of the coin is to expect unrealistically the experimental approach to solve all human problems. Even in the area of disease where the experimental approach has produced such brilliant benefits

many problems are not science-based. These would include cancer associated with cigarette smoking where motivation, not new knowledge, constitutes the deficit. In some hereditary diseases it seems unlikely that any method other than selective exclusion of marriages will be effective. And some aspects of pollution and environmental problems will depend primarily on social trade-offs, rather than on the development of new knowledge. In general, the really serious problems of man have been resistant to drastic political and economic remedies. In contrast there have been dramatic successes in research and technology, and as a result of these successes there is a growing demand that science solve the problems of humanity, even when there are questions that cannot be answered by science.

I spoke at some length on this subject at Woods Hole about a year ago. Alvin Weinberg has characterized this same theme as the need to distinguish between science and what he calls trans-science. While I have tended to use

examples from the medical field, he has used examples from his own field of nuclear energy. For example, he points out that in the important matter of setting acceptable standards for low levels of radiation, it would take 8 billion mice to establish a scientific answer, a number so large that clearly we have used and will use other ways at arriving at an answer. But in addition to those conditions in which he finds that science is inadequate simply because to get the answers would be unrealistically expensive, he also argues that science may be inadequate because the basic subject matter is too variable, such as in the social sciences, to allow rationalization according to the strict scientific criteria established within the natural sciences. Then too, science may be inadequate simply because the issues themselves involve moral and esthetic judgments, rather than scientific truths.

As we move into what is likely to be a period of even more active criticism of those in the health professions, it is essential that there be a clear understanding of the

nature and limitation of the role of medical research in solving health problems.

We at NIH are committed to carry out as effectively as possible not only those high emphasis programs growing out of an expert consensus of scientific opportunity, but also those programs where social need or public hopes are stronger forces in targeting than scientific leads. Population research, sickle cell anemia, arteriosclerosis and cancer are examples where mixture of both need and opportunity exists. There is, however, a tendency to confuse the new package--the targeted research program--as different in kind, less dependent on creative individuals and less dependent on strict use of the experimental method. Here the package must not be confused with the substance. The experimental method helps to find truth, not necessarily a social remedy, and experiments come out as they come out, not as we want them to come out.

The New Consumerism

I just mentioned that we are entering a phase of medicine in which I believe health professionals as individuals, and as groups, will come in for their greatest criticism since Hippocrates. Consumerism has extended far beyond thrifty bargaining at the market place. The movement has brought into question institutions, agencies, professions, and industries, and in many cases, rightly so. One effect of the questioning already is to expose the individual physician and the profession as a whole to a level of criticism sharper than at any time in the past. Physicians are experiencing this new adversary relationship in confrontations ranging from threats of personal malpractice suits to the questions "Why can't you cure my disease?" or "Why should you get rich off of my pain?" A simple but unsatisfactory defense is to engage in a defensive practice of medicine, prescribing extra laboratory tests and X-rays and unnecessary consultations more to protect the physician than his patients. It is little wonder that some professionals are discouraged and disappointed to find that

their altruism and above-average workload in this field of service seem to go unappreciated.

In the past, medical students and other health workers were warned to avoid becoming trapped in a self image of God-like proportions. Remember for instance, Robert Louis Stevenson's words, "There are men and classes of men that stand above the common herd; the soldier, the sailor, and the shepherd not infrequently; the artist rarely, rarer still, the clergyman; the physician almost as a rule. He is the flower (such as it is) of our civilization; and when that stage of man is done with, and only to be marvelled at in history, he will be thought to have shared as little as any in the defects of that period, and most notably exhibited the virtues of the race. Generosity he has, such as is possible to those who practice an art, never to those who drive a trade; discretion, tested by a hundred secrets; tact, tried in a thousand embarrassments; and what are more important, Herculean cheerfulness and courage. So that he brings air and cheer into the sick room, and often enough, though not so often as he wishes, brings healing."

Many of you who were attracted into medicine have with me some of the feeling of what Stevenson is saying. From time to time I have the privilege of talking with medical students. As one who has strayed into the area of public administration where criticism, fair and unfair, is well within the rules of the game, I have alerted them to the shock that they face as well, and have expressed my hope that in their reaction to criticism they can avoid cynicism which can be more destructive than egotism. I hope that the graduating classes of the seventies will not become entrenched in blind defense of the status quo. In that direction is stagnation.

But there is, as always, the other side of the question. When does consumerism intrude inappropriately into the area of expertise? The package labelled consumerism does not automatically insure truth. Selfish people for personal advancement fly under its banner but I am even more concerned about the misguided but well-motivated who feel that a pure heart can substitute for ignorance, an honest tongue

for lack of competency and clever criticism for substantive contributions. We must beware of those who seek only to destroy, not build, of those who depend only on the heart, not the mind in matters of health, but at the same time be alert to the truths that they also speak--that medicine is for people, not for doctors or other health professionals, and not for institutions or intellectual enjoyment.

The Hopes and Fears of Americans

The last area I want to discuss has to do with the hopes of the American people as they apply to health. In the field of medicine one can characterize the period between 1965 and 1975 as a time in which awareness of various health problems grew. Public anxiety from a variety of sources focused on inaccessibility, high cost and a growing confusions over the apparent incompatibility between modern miracles of health on the one hand, and the failure to resolve human problems on the other hand. Remember that in 1965, Medicare Medicaid, regional medical programs, comprehensive health, health research resources and the second phase of the health

professions education act which for the first time gave direct assistance to educational institutions--were all enacted. Much additional legislation as promissory notes to the American people has passed in succeeding years--most recently, for example, the comprehensive health manpower legislation of 1971, the new Cancer Act of 1971, the new Heart Act of 1972.

Not only has there been a probing within the executive and legislative branches of Government, but a cry of the times has been if we can put a man on the moon, let's cure cancer. Another has been the equally misguided suggestion, let's stop all research and use that money to cure people. Another trend has been the increasing anticipation that nothing short of major changes in financing, in distribution, and in organization, can be expected over the next few years. The national request for more health workers has led to increasing numbers of young people heading for health careers, especially as the job market in engineering and physics and school teaching seems to be constricting. It's led also to another serious dilemma. We are dependent on the graduates of foreign medical schools at the same time we are turning

away increasing numbers of qualified Americans from career opportunities in medicine. I do not think this country will long tolerate this situation.

Against this background of increasing dissatisfaction which some have called a national health crisis, there is a contrasting view suggesting considerable contentment despite the minor inconveniences of today. In health as in other fields those who have it made may want to keep it that way. Against this background, the health worker can be easily trapped. On the one hand, he's a have--perhaps the most have of all--from some of the statistics on job and income estimates. However, he is sworn by all that is decent in the whole history of mankind not to distinguish between the rich and the poor, the powerful and weak in matters of health. If I were completely honest with you, I might suggest that those of us in medicine think seriously about the quotation "it is easier for a camel to pass through the eye of a needle than for a rich man to enter heaven."

At this ceremony today, we recognize excellence and high achievement by creative, highly trained and experienced

individuals with all the pomp and tradition of academia. At the same time this institution has a long yet growing image of effective service--or as it is called today, community involvement. It is right and necessary that an institution such as this have the tools and capability to do both without sharp boundaries between the two. As one who has been interested in tissue culture and has filmed the activities of living cells, I was reminded on the way to this Convocation of that brief but essential moment in the life of all cells which is called mitosis or the similar sexual process called meiosis. The DNA which is normally organized throughout the nucleus of the cell suddenly condenses into chromosomes and then under the polar forces of two centripetal bodies at each end of the cell there is a dramatic separation with half of the DNA going to one side and half going to the other. Thus, the total accumulation of knowledge of the life processes is displayed in a brief essential and to me beautiful highly polarized condition. During this time, it should be pointed out, however, that the cell is not carrying out other functions and it is only when the redistribution of the DNA in close relationship with the functioning processes of the cell occurs

that it is able to carry out its special job. Thus, today, even while we look at this ceremony briefly in isolation the characteristics we honor are an integrated part of the life of our society. Thus, it is a joy to congratulate the recipients of these degrees and to say how pleased I am to be back and to wish this new institution the very best in the future.

#11-1

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET
OF THE NATIONAL INSTITUTES OF HEALTH ¹

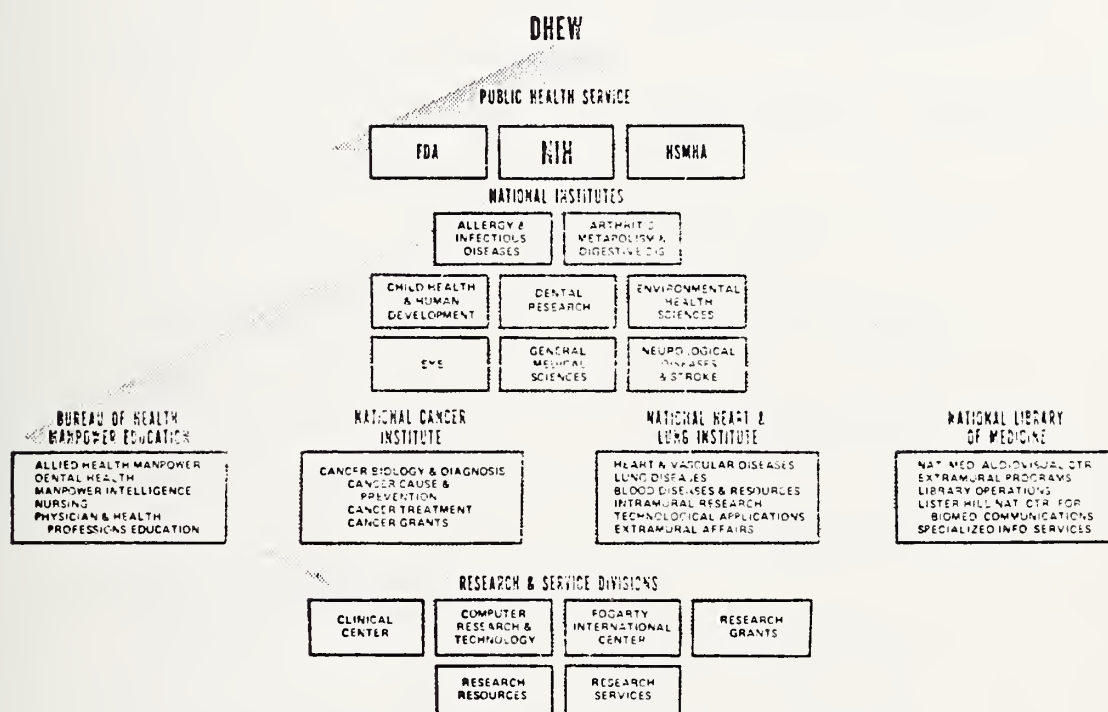
Robert Q. Marston, M.D.²

	<u>Page</u>
I. Organization of the National Institutes of Health	1
II. The Current Year (Fiscal 1973) Budget	3
III. 1973 Budget Authority	4
IV. Federal Budgets for Medical R&D, FY 1970-73	7
V. Legislation and Pending Bills	8

1 Prepared for presentation to the Association of Professors of Medicine at the Annual Meeting of the Association of American Medical Colleges, Miami Beach, Fla., November 5, 1972.

2 Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



Principal Officers, National Institutes of Health:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Leon M. Schwartz
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Thomas Malone
Associate Director for Collaborative Research	Dr. Leon Jacobs

II. The Current Year (Fiscal 1973) Budget

In view of the President's veto of the 1973 Labor-HEW Appropriation Bill, the National Institutes of Health will operate at the 1972 level under terms of a "continuing resolution" which expires February 28, 1973. In general, this will preclude the initiation of any totally new programs pending the passage and approval of a 1973 appropriation.

The following tables show a comparison of the 1972 Budget Authority with the original 1973 President's Budget. The amounts for 1972 deviate slightly from the actual appropriation since they have been made comparable to the 1973 estimate.

III. 1973 BUDGET AUTHORITY (in thousands of dollars)

<u>Activity</u>	<u>1972</u>	<u>1973 Estimate</u>	<u>Change over 1972</u>
<u>Research Institutes & Divisions:</u>			
Research grants.....	\$791,573	\$852,837	+\$61,264
Training grants and fellowships....	186,406	186,363	-43
Laboratory and clinical research....	114,945	121,160	+6,215
Research and development contracts..	232,181	263,054	+30,873
Collaborative research and support..	39,768	43,161	+3,393
Other direct operations.....	59,461	64,623	+5,162
Construction (Cancer).....	52,000	49,000	-3,000
Subtotal, Institutes & Divisions..	<u>1,476,334</u>	<u>1,580,198</u>	<u>+103,864</u>
<u>Bureau of Health Manpower Education:</u>			
Medical, dental and related health professions.....	469,795	344,560	-125,235
Nursing.....	144,399	122,934	-21,465
Public health.....	18,999	21,571	+2,572
Allied health.....	30,620	35,665	+5,045
Program direction and manpower analysis.....	9,749	8,898	-851
Other.....	<u>4,000</u>	<u>4,000</u>	<u>---</u>
Subtotal, BHME.....	<u>677,562</u>	<u>537,628</u> ^{1/}	<u>-139,934</u>
<u>National Library of Medicine.....</u>	<u>24,127</u>	<u>28,568</u>	<u>+4,441</u>
<u>Other.....</u>	<u>14,889</u>	<u>20,542</u>	<u>+5,653</u>
TOTAL, NIH....	<u>2,192,912</u> ^{2/}	<u>2,166,936</u> ^{2/}	<u>-25,976</u>

^{1/} Total funds available for obligation are estimated at \$608.0 million, including \$70.4 million for advance obligational authority, plus other carryover funds appropriated prior to 1973.

^{2/} Includes Cancer Research Initiative of \$378,885,000 in 1972 and \$432,205,000 in 1973. Excludes Scientific Activities Overseas funds of \$25,545,000 in 1972 and \$25,619,000 in 1973.

Highlights of the 1973 Budget

The President's 1973 budget for NIH provided an overall net decrease of \$26.0 million. This is the result of a requested decrease for BHME's programs due to a carryover of 1972 construction funds for obligation in fiscal year 1973. When viewed on an obligational basis, the decrease for BHME is \$11 million and the net increase in obligations for total NIH is \$135.4 million.

1. Research: The requested net increase over 1972 is \$103.9 million or approximately 7 percent. The major features of the budget for research are:
 - a. An increase of \$53 million in cancer research for continuation and expansion of the cancer research initiative, including the National Cancer Plan and construction of new centers and upgrading of present facilities;
 - b. An increase of \$22 million in heart and lung research, including such special areas as sickle cell disease, pulmonary diseases, arteriosclerosis and medical devices development;
 - c. An increase of \$6 million for expanded research in arthritis, kidney disease, diabetes and digestive diseases;
 - d. An increase of \$11 million directed at such activities as population research, mental retardation, sudden infant death syndrome and nutrition;
 - e. Except for the cancer initiative, no major change is being sought for research fellowships and training grants until studies underway reveal what the future course should be for these activities.
2. Health Manpower Education: The net decrease of \$139.9 million was requested based on the fact that no new construction grant funds were required because of the large appropriation in 1972 that allows for a sizeable carryover for use in 1973. Excluding construction, major features of the request are:
 - a. An increase of \$8.6 million for institutional support for medical, dental and related health professional schools including allied health and public health schools. The increase should help put the schools on firmer financial footing and the incentives for expanding enrollment and shortening curriculum should have the effect of producing more trained health personnel more rapidly;
 - b. An increase of \$5.9 million for student assistance to medical and dental students designed to provide support to a greater number of students and to provide support for the more flexible forgiveness and cancellation clauses contained in the Comprehensive Health Manpower Training Act of 1971.

3. National Library of Medicine: The requested increase over 1972 of \$4 million will provide two major features:

a. An increase of \$1.6 million for assistance grants to other medical libraries;

b. An increase of \$1.2 million for the Lister Hill Center which is dedicated to bringing modern communication technology into the service of practitioners and assisting to improve the medical services available in remote areas.

4. Summary: The following table is a summary by appropriation for the past, present and future years:

SUMMARY BY APPROPRIATION
(In thousands)

	<u>1971</u> <u>Comp.</u>	<u>1972</u> <u>Comp.</u>	<u>1973</u> <u>Estimate</u>	<u>Change</u>
<u>Research Institutes & Div.:</u>				
Biologics standards.....	\$8,725	\$9,294	\$9,528	+\$234
Cancer.....	232,969	378,885	432,205	+53,320
Heart.....	195,739	232,688	255,280	+22,592
Dental.....	35,704	43,404	44,415	+1,011
Arthritis.....	138,011	153,325	159,089	+5,764
Neurology.....	102,318	116,722	117,877	+1,155
Allergy.....	99,803	109,156	112,649	+3,493
General medical sciences.	159,886	173,472	175,960	+2,488
Child health.....	94,816	116,510	127,244	+10,734
Eye.....	31,178	37,132	37,384	+252
Environmental health.....	20,237	26,408	29,013	+2,605
Research resources.....	66,431	74,981	75,009	+28
Fogarty Internat'l Center	<u>3,732</u>	<u>4,357</u>	<u>4,545</u>	<u>+188</u>
Total, Institutes & Div.	1,189,549	1,476,334	1,580,198	+103,864
<u>Bureau of Health Manpower</u>				
<u>Education.....</u>	435,006	677,562	537,628	-139,934
<u>Nat'l Library of Medicine..</u>	21,510	24,127	28,568	+4,441
<u>Office of the Director.....</u>	10,498	11,324	12,042	+718
<u>Buildings and Facilities...</u>	<u>--</u>	<u>3,565</u>	<u>8,500</u>	<u>+4,935</u>
Total, NIH..	<u>1,656,563^{1/}</u>	<u>2,192,912^{1/}</u>	<u>2,166,936^{1/}</u>	<u>-25,976</u>

^{1/} Excludes amounts for the appropriation, "Scientific Activities Overseas" (SAO) which is shown with NIH for presentation purposes in the President's Budget. SAO is administered by the Office of International Health, DHEW.

IV. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1973

(in millions)*

Agency	<u>1970</u> actual	<u>1971</u> actual	<u>1972</u> est. obligations	<u>1973</u> obligations	<u>Increase</u> <u>1973/72</u>	<u>%</u> <u>inc.</u>
Total Fed.	<u>\$1,664</u>	<u>\$1,857</u>	<u>\$2,162</u>	<u>\$2,370</u>	<u>\$208</u>	<u>10</u>
Agriculture	50	60	65	72	7	11
AEC	104	105	107	115	8	7
DoD	125	124	124	137	13	10
Environ. Protection	-	13	17	20	3	18
DHEW** (NIH)	1,177 (873)	1,298 (1,039)	1,568 (1,266)	1,706 (1,369)	138 (103)	9 (8)
NASA	86	75	60	58	-2	-3
NSF	28	34	35	35	0	0
VA	59	63	68	75	7	10
Other	35	85	118	152	34	29

*Covers support of medical and health-related R&D (projects, resources, and general support including P.L. 480 funding for research) but not training or construction.

**FY 1970 includes those research programs transferred to the Environmental Protection Agency in December 1970.

V. LEGISLATION AND PENDING BILLS

- 1) P.L. 92-48
Fiscal 1972 Office of Education Appropriations
July 9, 1971
- 2) P.L. 92-52
HPEA Student Loan and Scholarship Extension
July 9, 1971
- 3) P.L. 92-69
Medical Information Exchange Extension
August 6, 1971
- 4) P.L. 92-80
Labor/DHEW Appropriations for Fiscal 1972
August 10, 1971
- 5) P.L. 92-86
National Science Foundation Authorization Act of 1972
August 11, 1971
- 6) P.L. 92-157
Comprehensive Health Manpower Training Act of 1971
November 18, 1971
- 7) P.L. 92-158
Nurse Training Act of 1971
November 18, 1971
- 8) P.L. 92-218
National Cancer Act of 1971
December 23, 1971
- 9) P.L. 92-255
Drug Abuse Office and Treatment Act of 1972
March 21, 1972
- 10) P.L. 92-258
Nutrition Program for Older Americans
March 22, 1972
- 11) P.L. 92-294
National Sickle Cell Anemia Control Act
May 16, 1972
- 12) P.L. 92-303
Black Lung Benefits Act of 1972
May 19, 1972

- 13) P.L. 92-305
National Institute of Arthritis, Metabolism, and Digestive Diseases
May 19, 1972
- 14) P.L. 92-306
Supplemental Appropriations Act, 1972 (Cancer)
May 27, 1972
- 15) P.L. 92-414
Cooley's Anemia
August 29, 1972
- 16) P.L. 92-423
National Heart, Blood Vessel, Lung, and Blood Act
September 19, 1972
- 17) P.L. 92-426
Uniformed Services Health Professions Revitalization Act of 1972
September 21, 1972
- 18) P.L. 92-449
Communicable Disease Control Amendments Act of 1972
September 30, 1972
- 19) P.L. 92-463
Federal Advisory Committee Act
October 6, 1972
- 20) P.L. 92-484
Technology Assessment Act of 1972
October 13, 1972

<u>BILL</u>	<u>SENATE</u>	<u>HOUSE</u>	<u>OUTCOME</u>
Appropriations for Labor/DHEW, 1973 (H.R. 15417)	(P) 6/27/72	(P) 6/15/72	VETOED 8/16/72
Appropriations for Labor/DHEW, 1973 (H.R. 16654)	(P) 10/3/72	(P) 9/19/72	(CP) 10/14/72
National Institute on Aging (S. 887, H.R. 14424)	(P) 9/21/72	(P) 7/18/72	(CP) 10/12/72
Multiple Sclerosis (H.R. 15475, S. 3659)	(P) 9/26/72	(P) 8/1/72	(CP) 10/17/72
Consumer Product Safety Act (S. 3419, H.R. 15003)	(P) 6/21/72	(P) 9/20/72	(CP) 10/14/72
VA Medical Schools (Manpower) (S. 2219, H.J.Res. 748)	(P) 4/27/72	(P) 7/19/71	(CP) 10/13/72
Emergency Medical Personnel Act Amendments (S. 3858, H.R. 16755)	(P) 8/18/72	(P) 10/13/72	(CP) 10/17/72
Welfare/Social Security (H.R. 1)	(P) 10/5/72	(P) 6/22/71	(CP) 10/17/72
Health Facilities, Health Manpower, & Community Mental Health Centers Act (S. 3716) (Allied Health)	amended (P) 9/20/72		*
Medical Emergency Transportation & Medical Services Acts (S. 3221, H.R. 12563, H.R. 12787)		H.R. 15859 (clean bill) (P) 10/2/72	*
Children's Dental Health (S. 1874, H.R. 10356)	(P) 12/10/71		*
Department of Human Resources (S. 1432, H.R. 6961, H.R. 6966)	(HB) 5/25/71	(HB) 6/02/71	*
Health Maintenance Organizations (S. 3327, H.R. 5615, H.R. 5766)	(P) 9/20/72	H.R. 16782 (clean bill) (AF) 9/19/72	*
D.C. Medical Schools (H.R. 13713)		(AF) 4/20/72	*
Health Science and Society Commission (S.J.Res. 75)	(P) 12/2/71		*
Public Health Personnel Traineeship Program Extension (S. 3441)	(P) 8/16/72		*
Medical Libraries Assistance Extension (S. 3752, H.R. 16933)	(P) 8/16/72		*

KEY: AF - Approved by Subcommittee for Full Committee

HB - Hearings Begun

P - Passed

CP - Cleared for President

* - Did not complete legislative process. Will need to be reintroduced
in 93rd Congress

MEDICAL SCIENCE, THE CLINICAL TRIAL AND SOCIETY*

Robert Q. Marston, M.D.
Director
National Institutes of Health
Bethesda, Maryland

There are several reasons for me to be pleased to be with you at the dedication ceremonies for the McLeod Nursing Building and the Jordan Medical Education Building. From the national standpoint, we have here highly visible, tangible evidence of progress toward a national goal to increase our capability to meet the health needs of the people, through combined Federal, State and local efforts. There are also personal reasons I am pleased to be at Mr. Jefferson's University today. I have had long and close friendships with many at the University--to name just two, President Shannon and Vice President Crispell. In addition, the first medical dean I can remember is Dean Jordan. As did many of my vintage in medicine, I used the textbook on histology authored by Jordan and Kindred. Also, Dr. Jordan provided me with one of my first difficult career choices--that of the choice between the University of Virginia School of Medicine and the Medical College of Virginia. I might add that thirty years later my son is attending the University of Virginia. Another reason for being

*To be presented at dedication ceremonies for the McLeod Nursing Building and the Jordan Medical Education Building at the University of Virginia, Charlottesville, Virginia, November 10, 1972.

pleased was to learn that my old friend, Dr. Thomas Hunter, has been conducting a series of socio-medical conferences covering the subject which I am addressing today.

This occasion provides an appropriate setting in which to speak seriously about some of the boundary conditions under which the students passing through these buildings will carry out their professional careers. I have only two basic themes. The first is to express my rededication and that of the National Institutes of Health to the principle of insuring that all individuals involved as subjects of medical research be as fully protected as humanly possible. The second theme is related--an emphasis on the need for experimentation with human subjects including an assertion that there is immorality in not carrying out necessary research involving human subjects. I believe we should look directly at the implications of the subject, its necessity and its hazards. Such a discussion inevitably raises a question of the welfare of the individual versus the welfare of society--a subject with which Mr. Jefferson struggled so effectively. Just as he continuously stressed the ultimate importance of the individual--so must we as we deal with the many facets of this issue.

The need for scientific knowledge is intensified today because doctors have never before been in a position to produce so much positive good on one hand, or harm on the other, through the double-edged potency of their therapeutic weapons. However, the issue is not altogether a modern one. According to Dr. William Rowe, the Emperor Napoleon Bonaparte once said "I do not want two diseases, one nature-made, one doctor-made." (1) Napoleon's pointed comment was sharper than he could possibly have known. The march of medical knowledge in the intervening years has expanded immeasurably the possibility of "doctor-made" disease.

Rene Dubos spelled out some of the specifics of the potential dangers from the tools of medical science in these words "who could have dreamt a generation ago that hypervitaminosis would become a common form of nutritional disease in the Western world?....and the use of x-rays would be held responsible for the increase in certain types of cancer? That the introduction of detergents in various synthetics would increase the incidence of allergy...that advances in chemotherapy and other therapeutic procedures would create a new staphylococcus pathology?...that patients with all forms of iatrogenic diseases would occupy such a large number of beds in the modern hospital?" (2)

This very progress is the compelling reason for a continuing and close examination of the relations between medical science and clinical trials--and other research involving human subjects. We are dealing with a dynamic, ever-changing base of substantive knowledge. Sometimes the progress of a research project itself moves the state of knowledge so rapidly that serious and involved ethical problems arise concerning the continuation of that same experiment.

For example, in Sir Austin Bradford Hill's article, "Medical Ethics and Controlled Trials," he described the complex situation which arose in a trial of long-term therapy using anticoagulants in cerebrovascular disease. He relates, "In previous uncontrolled studies there was a distinct if inconclusive suggestion in favor of their anticoagulants use, and sufficient indeed, to make a trial difficult. Yet when put to the test of a controlled trial, with the comparison of a fully treated group and a group given a dose insufficient to interfere with the clotting mechanism, it not only appeared that no protection was afforded against the recurrence of cerebrovascular accident, but there was a small but definite

risk of cerebral hemorrhage in the fully treated cases. Here we have an instance--and by no means unique--of the wheel turning full circle. At the start of the trial was it ethical to withhold the treatment? At its end, was it ethical to give it? It is very easy to be wise (and critical) after the event; the problem is to be wise (and ethical) before the event." (3)

Any discussion of the benefits of scientific investigation involving the use of human subjects brings to mind a graduate of this University's School of Medicine, Walter Reed, who received his M.D. degree at the age of seventeen. He became a national hero because of his contribution to the control of yellow fever. Every school child knows the story of how the construction of the Panama Canal was stopped because of devastation from yellow fever. In 1900, Walter Reed and his associates discovered that yellow fever is transmitted to a non-immune individual by means of a bite of a mosquito that had previously fed on the blood of someone sick with this disease.(4) What is not always remembered about this event is the serious ethical question that was raised by Dr. Reed's experiments. At that time, it was not known that experimental animals could be given the disease; therefore, human studies were necessary.

Army volunteers were both exposed to infected mosquitoes and given subcutaneous injections of virulent material. The subjects were aware of the risk, indeed, Dr. Lazear, the group's entomologist and bacteriologist, died after an accidental bite. None of the individuals living normally in non-risk areas could have been expected to benefit themselves from these experiments. It is highly unlikely that the experiments would have been permitted under today's guidelines. And yet the social benefits were great, the experiments were well designed and the moral implications were seriously considered at the time, and the results are part of our national history.

In shocking contrast is the example from American history of the result of treatment by unverified methods. The central figure is Dr. Benjamin Rush. His conduct in earlier epidemics of yellow fever was described by Dr. William Bean as "especially tragic because Rush treated literally hundreds of victims of the disease. His purging and bleeding became almost a routine premortal ceremony--the heroic aspects of Benjamin Rush, his many ideas about mental health, his signing of the Declaration of Independence, have made us forget the harm he did. His willingness to follow the guttering candle of ignorance, his

dogmatic conviction that he was right, his consummate ability to fool himself consistently helped to kill an unmeasured plenty of his patients in Philadelphia. That his motives were pure and serene constitutes another example of the unlimited capacity of man to fool himself." (5)

Let me turn from the past to focus on the essential need for research involving human beings. There are several obvious reasons why such research must be carried on. First, in many instances, there may not be a suitable animal model. Second, even if such an animal model exists, there always comes a time at which the test must be carried out in man. Even when the situation is as clearcut as it was when it became possible to prevent the death of experimentally infected mice by treatment with penicillin, it still was necessary to test the antibiotic in man. Medical history is full of examples in which the promise of animal experimentation failed to hold up in humans, or in which the results in man exceeded those that would have been predicted from animal experimentation. Finally, and most relevant to this discussion, is the need to test definitively in humans the procedures and therapies which are already part of the practice of

medicine. The potency of modern procedures and therapies is such that the experimental method is often the only effective way to determine if their benefits are outweighed by undue hazard.

The late Dr. George James, known as an advocate for reform in health services, stated the problem well in one of his last talks; "In the discussion of ethical considerations relating to clinical research," Dr. James said, "the rights of the unborn generations to benefit from the fruits of the research must also be weighed. It can be debated that no man today has the free and moral right to condemn his grandchildren to the same perils of disease to which he is exposed by virtue of the present lack of effective scientific information, and his failure to participate in a search for it. It would help greatly to educate the population about this principle if the defects in our present medical armamentarium are to be made evident." (6)

Dr. Archibald L. Cochrane has pointed out in his recently published book titled "Efficiency and Effectiveness" that the United Kingdom's National Health Service has in the main achieved its goal to make health services available and accessible to the

entire population at a cost that individuals could afford. However, he said the impact of the program on the health of the people of Great Britain was limited by the scientific base. In Dr. Cochrane's words, "There is a strong suggestion that the increase in input since the start of the NHS has not been matched by any marked increase in output in the 'cure' section. In the illustrative examples there were strong suggestions of inefficient use of effective therapies, and considerable use of ineffective ones." (7) A major theme in his book underlines the necessity of undertaking appropriate randomized clinical trials as a primary means for building the scientific base.

There are several key areas in which the equivalent of Benjamin Rush's well intended but disastrous actions occur or may occur today. I have already quoted from Bradford Hill concerning the use of anticoagulants in the prevention of stroke. We have recently concluded scientific studies in the use of oral hypoglycemic agents to control diabetes from which it has been possible to identify an increased risk from the use of such drugs. Studies concerning the side effects of smallpox inoculation, balanced

against the need for such inoculations in this country, have led to a modification in recommendations concerning the use of smallpox vaccine.

Each branch of medicine has similar examples demonstrating the role of ignorance as a dominant deterrent in the achievement of effective health programs.

Objective data on the hazards of medical practice are scarce. Such studies as we have can be over-interpreted in either direction. But let me give one example.

Gardner and Cluff have found in their review of prospective studies of adverse reaction in hospital patients that "with certain exceptions, the percentage of patients with untoward reactions to drugs in the hospital has ranged between 10 and 18 percent despite the wide variety of institutions and investigational methods." (8) Even when one accepts the fact that serious disease justifies measures that increase the risk of adverse reactions, these figures are sufficiently high for concern.

We stand today at a point at which there is a need and opportunity to strengthen markedly the scientific basis of medicine to the advantage of all. However, the need and

opportunity exist at a time when (1) there is a trend back to "trial and error medicine;" (2) there is a failure to recognize even in the health professions, as well as the public at large, the need for and the value of randomized clinical trials, and (3) there is increasing concern about the welfare of individuals involved as subjects in research. When all is said and done, there are really three ways for determining what actions to take in disease prevention, treatment or rehabilitation. First, is the logical extension of fundamental knowledge to its application in man--the movement from scientific theory to scientific practice. Increasingly in the future actions on this basis must be coupled with the practical demonstration of their effectiveness. For many years we knew that tobacco smoke contained potential carcinogens but until the evidence was gained that smoking does cause carcinoma of the lung in man, there was an insufficient basis to start a campaign to decrease smoking. We know today, as a result of epidemiological studies the risk factors which may account for 50 percent of heart attacks under the age of 65, but we must carry out through intervention trials, the crucial studies that will tell us whether elimination of such risk factors will, in fact, prevent heart attacks.

The second basis for making decisions is the empirical use of the results of experience, the experience of colleagues and teachers. Medicine has been particularly dependent on this type of wisdom and will be in the future. This accumulated wisdom may serve both patient and doctor well. However, it is a transient type of wisdom. It is the best that one can do under the circumstances, weighing all of the factors, but subject to modification when and if adequate information becomes available.

The third mechanism for making decisions is exemplified by the controlled clinical trial. Because such research tends to be long-term, difficult and expensive, the clinical trial is less understood and appreciated than the dramatic results of penicillin or a new vaccine. Further, the large clinical trial tends often to be unrewarding in a professional sense to the individual investigators who make up the scientific team. Although it is incompletely understood and incompletely applied, the clinical trial is the type of research on which we will become increasingly dependent as time goes on.

Let me turn now to my second major theme. How best can we be sure that we protect the rights of individuals involved in clinical research? Many of you in this audience are well aware

of the many articles and books on the ethical aspects of the use of human subjects for research. A number of bills relating to scientific experimentation with human subjects were introduced in the last Congress reflecting a growing interest in the subject. I am particularly anxious that at NIH we interpret and enforce reasonable policies derived from basic and universal moral tenets as well as from requirements for sound scientific work. It is important also that as we review our policies we take into account the changing social, technical and political trends and even economic developments. New dimensions in medicine itself are creating changes. For example, the basis for choosing recipients of kidney transplants was a nonquestion until such transplants became feasible. Now it is an ethical problem to be solved.

For more than a quarter of a century, the NIH has been the principal source of national support for biomedical research. We also conduct a very sizeable research program in our laboratories at Bethesda. Thus, we have a special responsibility for the ethical conduct of research involving human beings.

From the beginning of our grant programs in 1937, the NIH Councils have been sensitive to the risks involved in research project proposals, often denying such proposals when the risks were unacceptable.

About 1965, NIH led the way in the development of special policies and procedures to protect individuals involved in the experiments we support. Subsequently, we made clear our interest in the ability of institutions to monitor adequately processes they had set up to protect individuals regardless of the source of research support. Along this line I was particularly pleased recently to hear that the Association of American Medical Colleges had declared that the institutions making up its membership do carry a specific responsibility for the assurance of rights of individuals involved as research subjects, and even more recently the AMA-AAMC Liaison Committee on Medical Education has included such institutional competence as a matter to be considered in accreditation review of medical schools.

The current policy statement of the Department of Health, Education, and Welfare which is based on the NIH-developed statement emphasizes the grantee's basic responsibilities for safeguarding the subjects' rights and welfare and requires:

. That no grant or contract for such activity be made unless the application has been reviewed and approved by an appropriate institutional committee.

. That the committee determine that the rights and welfare of the subjects involved are adequately protected, that the risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained, and that informed consent is to be obtained by methods that are adequate and appropriate.

. That the committee be responsible for continuing review of the activity in keeping with its determinations.

To date more than 750 institutions have filed general assurances of compliance with DHEW policy. These assurances include a statement of principles or code which the institution will use to guide its reviewers. Further, the assurances describe the committee or committees that will carry out the review and their procedures.

The statement of principles relied upon by the great majority of clinically oriented institutions is the Declaration of Helsinki of the World Medical Association. The ethical principles set forth in the Declaration have been formally endorsed

by the American Medical Association and eight of its component research groups. It is probably the nearest thing to a universal ethical code. Some few institutions rely on the older Nuremberg Code, others on the British Medical Research Council's statement on Responsibility in Investigations on Human Subjects and, in a few instances, on a code which is peculiar to the particular hospital or school.

DHEW policy places strong emphasis on the need for breadth of review. It emphasizes that the institutional committee should have the professional competence not only to review clinical projects, but also to determine acceptability of the project in terms of institutional regulations, applicable laws, local standards of professional practice and community attitudes. National NIH review groups can provide in-depth scientific review, but they cannot provide the breadth of review possible in a Medical Center, which can assemble a local committee representing the full spectrum of medical disciplines, as well as "lay" representatives from medical administration, legal medicine, and from other segments of the surrounding community.

Recently the Food and Drug Administration issued its own peer review requirements paralleling the DHEW policy which governs NIH clinical research. The only significant difference is that it has made lay membership on institutional review committees a "must," rather than a "should." I would propose any future amendments to the DHEW policy include a similar change.

Our guidelines provide a high degree of flexibility for the institution in establishing its review procedures, but we insist that a responsible committee be established and that the committee adhere strictly to the three basic criteria I have already mentioned.

- . Protection of the rights and welfare of the subjects.
- . Weighing of risks against benefits.
- . Determination that informed consent is to be obtained by methods that are adequate and appropriate.

It seems obvious that the first two criteria are the most critical to the ultimate decisions of any review group. Whether or not consent is in fact informed, admittedly it is difficult to assess. We oftentimes are in an uncertain situation in which inadequate information, communication problems, and the inability of the subject to comprehend--or to read--or to listen--can be misleading.

In the chain of events stretching from the first biomedical research concept to ultimate delivery of improved medical services the most critical link often is the human research subject. If through lack of care or an excess of zeal of the investigator and his interests we allow abuse of the human subject we endanger the beneficial forward march of research and fail ourselves as professionals.

Has the NIH policy been successful? We believe it has. It has demonstrated that good science and high standards of ethics are closely linked. Indeed, the presence of risk places a special demand on us that only the highest quality of research be tolerated. The NIH policy has introduced a new sensitivity to the protection of individuals at every step in the process from the preparation of research proposals through the development of local institutional policies, the review at the national level by our Study Sections and Councils, as well as in the development of national public policy concerning biomedical research. The applications involving questionable procedures--never many--have become noticeably fewer in the past six years. However, we still interpose our judgment by disapproving applications (about 1½%) because of hazards, and we know that as new methods are learned,

and new insights are gained, we will face additional agonizingly difficult decisions.

However, even as I assert that the NIH-DHEW policy has been effective, I believe that more discussion, more visibility and clarification of the guidelines in some areas is needed today. Our policy is essentially egalitarian. It makes no distinctions as to race, color or socio-economic status. For instance, it touches only lightly on the handling of subjects with what it calls "limited civil freedom," a classification which includes prisoners, and residents of institutions for the mentally retarded and mentally ill, and minors.

The policy assumes that the medical scientist similarly makes no distinctions in the choice of research subjects, except as his research interests are in diseases of a particular race, common in a certain socio-economic group, or limited to a particular hospital or institutional population.

Unfortunately, this is not always the way it appears. Even more unfortunately this is not always the way it is.

Many of our major research institutions are located in the large cities and their patients are drawn primarily from the

disadvantaged groups crowded in the center city. Thus, their research tends to be concentrated in these groups.

Medical research trials frequently require that a convenient stable subject population be followed over a period of weeks or months rather than days or hours. The medical scientist naturally turns to groups whose availability can be controlled--hospitalized patients, institutionalized patients, medical students, and prisoners. Much research, particularly that which involves appreciable risks and requires frequent monitoring, is concentrated in such groups.

I believe that the time has come when we must recognize that the risk of involvement in research is not distributed as uniformly among the nation's citizens as is the possibility of benefit from the products of this research. However, I expect that the Assistant Secretary's commission reviewing the Tuskegee Study will ultimately address itself to certain aspects of the problem of research using the disadvantaged as subjects.

At this time, as I speak more specifically about some plans and proposals, I want to make clear that I am primarily concerned with those situations where some significant risk is involved in research with human subjects. My comments will concern three general proposals:

1. To develop regulations to strengthen the protection of subjects having "limited civil freedom," and to convene a series of workshops broadly representative of all concerned groups to discuss and refine the regulations and implementing guidelines. The first such workshop is scheduled for early February.
2. To undertake an examination of possible methods of compensation for subjects who, in spite of all precautions, are harmed by research activities.
3. To realert the scientists and administrators concerned with the research process, and to generate greater visibility for existing regulations and procedures. One way will be by insuring that all applications involving significant risk be specifically flagged for the attention of Advisory Councils throughout NIH. Let me reemphasize that while the requirement of high quality has characterized all of NIH programs, there is a special need to insist that the quality of research design and a high probability of obtaining definitive answers must receive special consideration where potential hazards to humans are a part of the price of doing the research.

The additional regulations which I propose will be developed in consultation with affected agencies of the Department of Health, Education, and Welfare, particularly the Health Services and Mental Health Administration. Such regulations would govern the conditions under which an NIH grant or contract may be awarded for research involving inmates of prisons and correctional institutions, as well as hospitals for the mentally ill and retarded.

If research is being done in such an institution under an NIH grant or contract, assurances would be required from the grantee/contractee (e.g. medical school) as now required and in addition from the institution when the work is done (e.g. correctional institution). Similarly, the institution where the work is done would now be required to establish suitable broadly-based institutional committees with the responsibility and expertise for reviewing research proposals and for assuring compliance with DHEW policy.

Any financial compensation to subjects would be reasonably related to the prices paid for other services and not be so high as to constitute undue inducement. We would require a clear statement

that neither participation in the proposed research project nor withdrawal from it will materially affect the conditions or terms of any subject's institutional confinement.

In the case of the hospitals for the mentally ill and retarded, the research supported would be restricted to that which (a) is directly concerned with the issues of mental illness, mental health or mental retardation, or (b) will potentially benefit primarily a class of persons commonly confined to a hospital for the mentally ill or retarded, or (c) which will lead to such knowledge important to the prevention of mental illness or retardation that may reasonably be expected to reduce the need for such hospitalization.

Special attention will be given to the requirement for informed consent embodying all of the basic elements in current DHEW policy with special provisions to make sure that the risk-benefit balance is understood by the subject and that no undue inducement be offered.

I would not like to depart from the subject of research involving children without commenting on the peculiar conflict

between the medical needs of children as a class and the requirements of our laws. It is a medical truism that children are not small adults. They have their own diseases, they react differently to what are thought of as adult diseases and they do not react in the same fashion to treatment. The Food and Drug laws require that drugs be tested in all age groups for which a drug is intended.

Yet, under English common law, no parent, no next of kin, or legal guardian can consent to the involvement of any child in a research project not intended for the good of that particular child. Thus, the law is not entirely consistent with the needs of children as a class, and particularly with the needs of mentally retarded children.

Guidelines to be derived from the regulations I plan to propose, as well as the practicality of setting similar guidelines for other subject groups, will be discussed in detail at a series of workshops planned for the coming months in Bethesda.

We plan to bring together research scientists, research administrators, lawyers, clergymen and others concerned with ethical matters, and representatives of other specialties. We

will discuss the varieties and limitations of informed consent, the impact of consent procedures on the design of research projects, and the possibility of providing compensation to subjects who incur injuries in the public service. I do not intend, however, to wait until these discussions are completed before initiating changes.

As I have said, we plan to require special procedures where experimentation with human subjects is carried out under conditions in which meaningful informed consent is difficult to achieve. I am initiating three other actions. First, my staff is reviewing recommendations made by members of Congress and experts in the field many of which were embodied in recent legislative proposals. We will focus our immediate attention on those measures for the protection of research subjects which can be adopted by administrative action. Secondly, we have initiated an examination of possible mechanisms for fair and equitable compensation for subjects who despite all of the precautions we can take are harmed as a result. Third, we will give especially careful consideration to any proposal for research in which participants are exposed to risk when they themselves do not have reasonable chance of benefitting from such experiments. Under such conditions we will require special justification in terms of significant benefit to humanity.

As I said earlier, if, in a specific case, I were forced to choose between the individual and the general welfare of society, I would choose to protect the individual. But, in the real world we must have both individual and social welfare. And in the real world, the day by day decisions are not made in Washington, nor can they be guaranteed by assertions by the Director of NIH nor the Secretary of HEW. We believe that the responsibility ultimately must rest with the individual institutions, such as the University of Virginia, as well as with the individual investigator and physician. Our job at NIH is to supply unequivocal guidelines to monitor clinical research and to do all within our power to prevent clear abuses. The guiding principle for physicians down through the ages has been the dictum "first of all do no harm." To the students who pass through this Nursing Education Building and this Medical Education Building this dictum will be far more demanding than in the past. While they maintain a sensitivity to the possible adverse effects of their therapies, they will also be required to have an increased appreciation of the need to replace ignorance with knowledge. And the new knowledge, which will benefit all of society, must not be gained at the expense of any individual or any segment of society.

REFERENCES

1. Quoted in "Iatrogenic Disease," William S. Rowe, The Medical Journal of Australia, September 13, 1969, Vol. 2, p. 560.
2. Forepage - The Complications of Modern Medical Practices, David M. Spain, 1963.
3. "Medical Ethics and Controlled Trials," Sir Austin Bradford Hill, The British Medical Journal, No. 5337, p. 1043, April 20, 1963.
4. Reed, W.; Carroll, J., and Agramonte, A.: "Etiology of Yellow Fever: An Additional Note. Journal of the American Medical Association. Vol. 36, 431-440, Feb. 16, 1901.
5. William B. Bean, the Archives of Internal Medicine, Vol. 117, p. 1, 1966.
6. "Clinical Research in Achieving the Right to Health," Dr. George James, the Annals of the New York Academy of Sciences, Vol. 169, p. 301.
7. Cochrane, A.L.: "Efficiency and Effectiveness, 1971, p. 67.
8. Pierce Gardner and Leighton E. Cluff: "The Epidemiology of Adverse Drug Reactions. A Review and Perspective." The Johns Hopkins Medical Journal, Vol. 126, p. 77.

SELECTIVE BIBLIOGRAPHY

- . DAEDALUS, Spring 1969
- . Experimentation with Human Subjects, Paul A. Freund 1970.
- . Clinical Investigation in Medicine, Legal, Ethical and Moral Aspects, edited by Irving Ladimer and Roger W. Newman, 1963
- . Report of the Round Table Conference on Biomedical Science and the Dilemma of Human Experimentation held at the 7th General Assembly of the Council for International Organizations of Medical Sciences, 1967.
- . Philosophy and Ethics of Medicine, Michael Gelfand, 1968.
- . Experimentation with Human Beings, J. Katz, 1972.
- . "The New Dimensions In Legal and Ethical Concepts for Human Research." Annals of the New York Academy of Sciences, Vol. 169, Jan. 1970.
- . "Early Diagnosis of Human Genetic Defects--Scientific and Ethical Consideration" Fogarty International Center Proceedings. No. 6, 1972.
- . Report of Joint Hearing on "National Advisory Commission on Health Science and Society" (S.J.Res. 75) Committee on Labor and Public Welfare. U.S. Senate. U.S. Government Printing Office 1972.
- . "Clinical Pharmacology in the Human Volunteer" Journal of Clinical Pharmacology and Therapeutics. Vol. 13, No. 5, Part 2, Sept.-Oct. 1972.

RECENT LEGISLATIVE PROPOSALS RELATED TO THE ETHICS
OF RESEARCH ON HUMAN SUBJECTS

- S.J.Res. 75 -- National Advisory Commission on Health Science
and Society.
(3/24/71) Mondale (Bayh, Brooke, Case, Fong, Harris, Hart,
Hughes, Humphrey, Javits, Kennedy,
McGee, McGovern, Moss, Nelson, Pell,
Randolph, Schweiker)
- S. 3935 -- To amend the PHS Act to provide for restrictions on
funds for experimental use. -- Javits
(8/17/72)
- S. 3894 -- To amend PHS Act to provide for reservation of funds
(8/8/72) for research into the possible social consequences
of biomedical technologies. -- Tunney
- S. 3951 -- To establish within the executive branch an independent
(9/5/72) board to establish guidelines for experiments involving
human beings. -- Humphrey
- H.R. 16593 -- Dept. of Defense Appropriations -- Senator Kennedy
introduced an amendment on October 2, 1972 --
None of the funds appropriated by this Act shall
be available for any research involving un-informed
or non-voluntary human beings as experimental
subjects.

FAREWELL ADDRESS

Robert Q. Marston, M.D.
National Institutes of Health, April 27, 1973

It was in the early fall of 1965 that Jim Shannon offered me the job of Associate Director of NIH for the "next two or three years." I commuted back and forth during that fall recruiting the initial staff for Regional Medical Programs and making the transition from academia to Federal service. The "two or three years" have now grown to almost eight years, and when added to the two years that I spent here in the early fifties makes it not only the longest time that I have ever served one institution--but as I have said elsewhere, clearly NIH has been the dominant institution of my professional career.

I have thoroughly enjoyed each aspect of my experience here: intramural scientist; chairman of an outside advisory committee; Associate Director for Regional Medical Programs; again Associate Director, NIH and Acting Director of the National Institute of Neurological Diseases and Stroke; and of course Director, NIH. In addition, for a period of about one-half year I was Administrator of Health Services and Mental Health Administration. During that exciting period, however, I continued to attend Shannon's staff meetings because the Regional Medical Programs was not actually transferred to HSMHA until about that time that it was decided that I would become Director of NIH.

With so many jobs and so many bosses, it's dangerous to begin naming names. But of the five HEW Secretaries--Gardner, Cohen, Finch, Richardson and Weinberger--I obviously have worked most closely with Wilbur Cohen and Elliot Richardson. I respect both greatly, and enjoyed

immensely the working relationship that I had with each. Thus you can understand how much I appreciate the kind words which John Sherman has quoted from Wilbur Cohen and the letter from Elliot Richardson from which excerpts were published in the NIH Record this week. It is worth noting here, that both of these men have, to a high degree, that absolutely essential quality for any Secretary of HEW--a deep concern for and a sensitivity to the needs of people, especially those who may be handicapped by problems of health, ignorance or poverty. Ultimately those responsible for the Nation's health, education and welfare programs both in the Executive and Congressional branches must project to the Nation at large both the image and the reality of such concern and sensitivity.

When I think of other names that should be mentioned today, I run into a serious dilemma. Jim Shannon, John Sherman, and Bob Berliner of course; my immediate OD Staff; Institute and Division and Bureau Directors; intramural, extramural program people--in all more than 10,000 people here at NIH alone, not to mention our whole advisory structure, and then, too, those many individuals from other parts of government--especially my friends from HSMHA and the Department. Nor could I let this time pass without a very special word of appreciation to those members of Congress with whom I've worked over the years--I can only say, "Thanks to all of you for making this the stimulating, exhilarating, experience that it's been for the last eight years." It's been a period of high purpose and great accomplishment in an atmosphere of mutual trust and pleasant associations. It has been a

happy place with happy people. Yet if I had to choose a single word to describe NIH, it would have to be the word "quality".

Now I would like to say a few things about NIH, and its future and your future. In so doing it becomes very hard not to repeat things that I have said over and over again as Director of NIH. Indeed, I am a bit embarrassed to find that my speeches fill six rather large filing cabinets. I find in looking over this accumulation that there is almost nothing that I need to say as a private citizen which I did not say as Director of NIH. Thus this public record does spell out, I believe, my strong support--

- . . . for the intramural program of NIH
- . . . for the new, young scientists, and for their preparation through the training grant mechanism
- . . . for the peer review system which has evolved over the years
- . . . for basic research, and particularly the principle that applied research should not be expanded at the expense of basic research
- . . . and for a balanced biomedical research program--
for example, cancer research should not be increased at the expense of other fields of biomedical science

and this record also expresses my strong conviction--

- . . . that scientific management is more important than the blind application of a system of management

- . . . that creative people are to be valued more than organizational arrangements or complex plans
- . . . and that criticism is a necessary part of science to be encouraged and not stifled.
- . . . and that the Library of Medicine is a gem in NIH and in the Nation.

Finally I have taken a special and personal pleasure, because of my own background in education, in working with the Bureau of Health Manpower Education in the difficult job of defining and implementing Federal policy in the area of education for health professionals.

In looking over some of these accumulated documents, I hope that some of my personal philosophy about the relationship of people to people comes through. Perhaps I speak too much from the idealism of one who chose to go into the medical profession, but I believe in the dignity of man--that to treat one another with respect is an expression of strength, not weakness; and that charity is good, not bad; that the power of public office should not be allowed to lead to arrogance; and that we must always remember as public officials that the money we spend is not our own.

I find it somewhat strange to be repeating this litany to you as I leave NIH, and I truly hope that events in the future will prove this to have been an unnecessary exercise--that people in the future, looking back on these statements, will even find them a rather pious, obvious list with which no one could disagree. Yet I repeat the points

not as abstract items of philosophy but because of specific concerns often surrounding a specific action or statement within recent months.

Let me say again at this point that I thoroughly enjoyed my work at NIH during the first Nixon Administration, and during the latter part of the Johnson Administration. I have no ax to grind. But I know that you have concerns about some of the points that I have touched on. Let me suggest that you view your concerns against the following background. Dr. Hoagland, Director of the Worcester Foundation, in an article entitled, "Anti-Science--a Growing Danger to America's Health and Pocketbook," makes this comment: "It has taken a quarter century to build up the National Institutes of Health. The support of research has been a model other countries have imitated. The peer review system has given us the best science through a Federal agency with the least political interference of any governmental process ever developed. It is truly one of the great achievements of American government but it is being destroyed."

To the extent that you believe as I do in his basic statement about the importance of NIH, let me urge you to do the following three things: Continue to speak out your beliefs constructively. This is a nation of checks and balances, of free people, and as such it is totally dependent on the willingness of honest men and women to speak honestly their best judgments. This is particularly true in the area of science where hopeless confusion is the inevitable result of distortion of truth.

Nations have struggled for years with the problem of maintaining objectivity and the ultimate test of truth in the conduct and the management

of biomedical research as that research has been supported increasingly with public funds. The solution in most countries except our own has been to separate medical research from the direct control of Government because of the conviction that the political process is inherently incapable of resisting the temptation to misuse science for its own immediate political needs. Thus, throughout Western Europe the Medical Research Councils tend to be autonomous or semi-autonomous bodies supported by Government, but not controlled by Government. Even in a country such as the USSR, the Academy of Medical Sciences and not the Ministry of Health, has the major responsibility for the conduct and support of such research in the USSR.

In this country, so far at least, enlightened leadership in both the Executive and Congressional Branches have resulted not only in a sound and healthy growth in biomedical research, but in minimum of attempts to bend science to meet short-term political needs. Of course, a major check on such temptations have been the existence of the NIH peer review system.

This necessary freedom to conduct research in a free environment is sometimes being misunderstood as advocacy for special interest groups on the one hand, and potential disloyalty on the other. Such a misunderstanding could result in what has been feared in other countries, that is a distortion of truth--a substitution of bias for objectivity. Thus, there is a special need today for you to continue to provide your candid professional judgments. Anything else can lead only to outright chaos and would be a serious disservice to the Nation you serve.

Second, do not become too discouraged. I remind you that in 1968

when I became Director of NIH, many people, including the then-President of the United States, commented on the difficulty of the job. Many thought then, as some think now, that the only possible role for NIH was a downward one. Instead, the past five years has been a period of major substantive progress. Indeed, as short a time as a year ago, I was able to tell the appropriation committees of Congress that fiscal 1972 had been a good year for NIH. For the Marstons at least this period has been a sort of Shangri-la with a purpose. The work of the NIH is measured in decades and generations, not in weeks, months or even years. No Institution in the world, to my knowledge needs less to be defended. So long as its aspirations remain so high and its accomplishments so unquestioned by competent people its course must continue to be upwards. Of course, as Representative Roy, a physician on our legislative committee, said recently in contrasting the different magnitude of work required to build up rather than discontinue programs, "Any jackass can kick down a barn but it takes a carpenter to build one." Thus one does have to remain alert to attack from the ignorant or intentionally destructive.

Finally, remember the human values. We are dependent on the work of great scientists here and throughout the nation, on teachers and professional people of all levels, but we are also dependent on those who in doing lesser tasks will make it possible for these with special gifts to utilize those gifts optimally. There is unfinished work to be done in the area of equality of opportunity, of abolishment of prejudices

of various kinds. Then, too, there will be the invitation to copy harshness and insensitivity that may be seen elsewhere. Times of crisis always bring pressures for friends to fight friends, to forget the broader enemy of disease and ignorance, and to strike out for trivial reasons at those close at hand.

Last week at the Institute Director's meeting I made a special plea that as the Office of the Director, NIH, carries out its necessary role of serving as something of a buffer between "NIH internal" and "NIH external" that people remember the special strains that John Sherman and Bob Berliner have in this interim period, and continue to give them the type of support given me. I am of course keenly disappointed that the promise in December of a new and fully qualified Director of NIH has still not been fulfilled by May. I do not know how long this delay will continue, but I urge you to support each other and to continue to support John and Bob during the interim.

John Gardner has said that institutions can, in contrast to individuals, age without losing their vigor and effectiveness. They are revitalized by the addition of new people. NIH can continue to evolve as it has done over the past decades, by maintaining its flexibility in the development and implementation of its programs. It needs the competence of the experienced and the vigor and enthusiasm of the new initiates. Today especially, it needs all of you to continue to pull together for the good of the Nation.

Finally let me say how much Ann and I are looking forward to the next phase of our career--that of taking a sabbatical year, as a Scholar-in-Residence at the University of Virginia and a Distinguished Fellow at the Institute of Medicine of the National Academy of Sciences.

May 25, 1973

Dr. Emmett B. Carmichael
Editor
ALABAMA JOURNAL OF MEDICAL SCIENCES
University of Alabama Medical Center
1919 Seventh Avenue, S.
Birmingham, Alabama 35233

Dear Dr. Carmichael:

Dr. Robert Q. Marston has asked me to submit for publication his enclosed article "The Relation of Science to Medicine." This is essentially the paper he presented at the University of Alabama on May 3.

If I can be of help in the editing process, please call 301-496-4591.

Dr. Marston can be reached at the following address:

Institute of Medicine
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

His telephone number at the Institute of Medicine is 202-961-1876.

Sincerely,

Enclosure

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THE RELATION OF SCIENCE TO MEDICINE¹

by

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Ladies and Gentlemen: For the first time in almost fifteen years, I find myself in the rather comfortable position of making a speech not as the head of an institution. My current titles have the comfortable ring of scholar and fellow.

Why do I start ^{this} off ~~a~~ lecture ~~entitled "The Relation of Science to Medicine"~~ with such foolishness? First, because I do feel a bit of relief, though certainly my experiences as a dean and in various capacities in the Federal Government have been anything but oppressive and I am not by nature one who shrinks from speaking his mind. Another reason is that one of the important roles of science in medicine is to act as a check against the introduction of bias, prejudice or personal preference in medical practice. Indeed, this is the aspect of science in medicine that I would dwell on most this afternoon, for I shall be talking primarily about clinical trials--about the need for them, the difficulties associated with them, and the general lack of understanding of their nature. But before doing that let me revert to my former role of Federal bureaucrat and bring you a few words from Mr. Washington's City on the Potomac.

Over the years, I have always organized my comments in three general areas: 1) organizational and personnel changes, 2) legislative and programmatic changes, and 3) budgetary matters. First, the question, Are we organized yet? Sometimes, in looking at European nations, one is amazed at how long it takes to organize a new government. For instance, in Holland it has now been four months since the election, which required a compromise government. The new government has not yet been formed; cabinet ministers are all in an acting capacity. ^{But we do} ~~We do~~ things differently in this country. Or do we?

Time magazine reports that six months after the November election, eight of the eleven assistant secretaries and agency heads introduced at a recent award ceremony were still in an acting capacity. In the health area, there is no Director of NIH, no Administrator of HSHMA, and no Commissioner of the FDA; and Dr. Edwards was ^{only} sworn in as Assistant Secretary for Health within the last two weeks. Inevitably, this type of management problem in a department that has had five Secretaries and four Assistant Secretaries for Health in the last five years continues to raise problems of program implementation at the national as well at the local level. As a citizen, I hope, as I am sure you do, that these key vacancies will be filled in the near future.

On the legislative front the report is quite simple. No significant new legislation has been submitted by the Administration. The major approaches this year are to encourage lapsing of existing unneeded legislation.

Little can be said at present about the appropriation situation, in view of the keen battle over the control of the purse that is going on between the Executive and Congressional Branches--with, in one instance at least, the third branch of government, the Judicial Branch, having stepped in to decide the fate of some of the OEO programs.

At NIH, the process of phasing out training grants, general research support grants, and various components of the manpower program is well under way. Cancer research support is being increased significantly, albeit accompanied by comparable offsets in the budgets of other Institutes, with the exception of the National Heart and Lung Institute, which has a modest increase.

There is much discussion about new ways of doing business--decentralization, regionalization, even possible modification of the peer review mechanisms. A committee ^{has prepared} ~~is considering~~ reorganization of the Health Services and Mental Health Administrative. Efforts are being made to streamline ~~and to make~~ the Federal bureaucracy ^{--to make it} more efficient and smaller.

Almost every item I have mentioned is a subject of some controversy.

If I seem to be treating some of these items with too light a touch, let me assure you that my own experience of ten years in the Federal Government has been so enjoyable, so productive and so stimulating that ~~in all seriousness~~, I would urge that at least some of you think seriously about spending some time in Washington, should you have the opportunity. My enthusiasm for this runs so high that I will be spending part of my time at the Institute of Medicine of the National Academy of Sciences, setting up a program for young people to spend a year in public policy fellowships in the Federal Government. Indeed, I ~~would~~ ^{believe} ~~go so far as to say that~~ it is essential that talented people with experience in areas outside the Federal Government ^{should} help find solutions to some of the major health problems that will involve Federal action in the next few years.

It has become increasingly difficult to talk about any part of medicine without considering the Federal role in one way or another. For example, the relation of science to medicine requires today some type of assessment of the Federal role, both in concept and practice. The concept of the Federal Government as the dominant patron of ~~our~~ medical science has not been seriously questioned by any Administration since World War II, but there have been increasing, and as yet

unresolved, debates about how such patronage should be managed. These debates have occurred in recent years in all countries with significant biomedical research programs. I have had occasion in recent years to work closely with medical research councils throughout western Europe, and ⁱⁿ ~~with~~ Japan, the USSR, and various other eastern European nations. Across this ~~full~~ array of different forms of government of large and small countries, there is a striking similarity in discussions about the relationship of science to medicine.

These discussions are complex, and one attempts to display them in simplistic terms only at great risk, but the more fundamental questions concern the varying interpretations of where we stand in our knowledge of biological events today and of what the prospects are for the immediate future. Most of us in the science field, whether in a small country of four and a half million people such as Denmark, or in a large country such as the United States, feel that this question of the "state of the art" is critical. But the problem can be approached from another ^{point--namely,} ~~view--the view~~ that societal problems in the health field are so urgent that, regardless of the current "state of the art," short-term highly directed research must take precedence. From these two basically different starting points arise most of the debates that have raged in recent years.

The questions include: What proportion of a ~~Nation's~~ income should be allocated to research in health, in contrast to more immediate organization and delivery problems? What is the relative priority of health versus transportation, education, food, clothing, housing, and other ^{demands?} ~~desirables?~~ Within the research dollar, what proportion should

go for basic research? ~~What proportion~~^F for applied research? How should research be managed? To what extent by scientists? and to what extent by managers who are not expected to understand the substantive issues? What instruments are preferable--contracts, grants, Federal laboratories? And one could go on.

There is ^{an} even ~~broader~~ bias that reaches ~~even~~[^] to the heart of the democratic process. Let me read from an address given by the Under Secretary of HEW on April 25. I want to confine my disagreements with his views to the area of biomedical research. Mr. Carlucci said:

There are two schools of thought. . . . One says that a public agency should be a primary advocate of the special group of citizens that it serves. The other holds to the belief that a public agency must serve first and always the broad public interest, and take its direction and policy from the duly elected leader of the executive branch of government--be he president, governor, mayor or county supervisor. My beliefs, and those of Secretary Weinberger, rest clearly with this latter view. To me, public advocacy by a public agency is outright chaos. Sooner or later it places that agency in an adversary position with the chief executive.

The Under Secretary is clearly talking of the broader functions of government, but in my view he is badly off base if he includes in that broader definition the conduct and management of biomedical research. For here, there is a different, perhaps larger truth for which the chief executive and his immediate political advisers^e have limited competence. Nations have struggled for decades with the problem of maintaining objectivity and the ultimate test of truth in the conduct and management of biomedical research as it has been supported increasingly with public funds. The solution in most

countries except our own has been to separate medical research from the direct control of government, because of the conviction that the political process is inherently incapable of resisting the temptation to misuse science for its own immediate political needs. Thus, throughout western Europe, the medical research councils tend to be autonomous or semi-autonomous bodies supported by the government, but not controlled by government. Even in the USSR, the academy of sciences and not the ministry of health has the major responsibility for the conduct and support of such research.

It is only because this country has so far been fortunate enough to have enlightened leadership in both the Executive and Congressional Branches--which have recognized the essential need to draw on ^{experts} ~~advisors~~ with more competence than the Chief Executive or his immediate ~~advisers~~ ~~staff~~ -- that we have been able to have both a healthy growth in biomedical research and a minimum of attempts to bend science to meet short-term political needs. Of course, a major check on such temptations has been the existence of the NIH peer review system.

This necessary freedom to conduct research in a free environment is sometimes misunderstood today as advocacy for special interest groups on the one hand and potential disloyalty on the other. Such a misunderstanding could result in what has been feared in other countries--that is, a distortion of truth, a substitution of bias for objectivity.

Turning to more specific questions about the relationship of science to medicine in this country, let me repeat for you my own

biases expressed in my farewell address at NIH last week. They read as follows:

My public record does spell out, I believe, my strong support for the intramural program of NIH; for the new young scientists, and for their preparation through the training grant mechanism; for the peer review system which has evolved over the years; for basic research, and particularly the principle that applied research should not be expanded at the expense of basic research; and for a balanced biomedical research program--for example, cancer research should not be increased at the expense of other fields of biomedical science. And this public record also expresses my strong conviction that scientific management is more important than the blind application of a system of management; that creative people are to be valued more than organizational arrangements or complex plans; that criticism is a necessary part of science, to be encouraged and not stifled; and that the Library of Medicine is a gem in NIH and in the Nation.

Finally, I have taken a special and personal pleasure, because of my own background in education, in working with the Bureau of Health Manpower Education in the difficult job of defining and implementing Federal policy in the area of education for health professionals.

I added, in a different vein:

In looking over some of my accumulated public documents, I hope that some of my personal philosophy about the relationship of people to people comes through. Perhaps I speak too much from the idealism of one who chose to go into the medical profession, but I believe in the dignity of man--that to treat one another with respect is an expression of strength, not weakness, and that charity is good, not bad; that the power of public office should not be allowed to lead to arrogance; and that we must always remember as public officials that the money we spend is not our own.

That I believe these things does not make them true, of course, but they do constitute a general consensus of the scientific community in this country and probably in the world. Those outside of the scientific and professional fields have tended to take a somewhat different view, as I have said. But let us leave now some of these questions of broader public policy in science.

Within the field of biomedical science itself, the type of science that is easiest to accept and apply is that which leads to a vaccine to prevent a disease, to antibiotics to cure a disease, to hormones to replace deficiencies, or ^{to} operations ^{correct deformities or} to remove diseased tissues, ~~or correct deformities~~. The situation becomes somewhat more difficult when unusually sophisticated treatment or knowledge is required. Thus the statistics in centers that carry out open-heart surgery on a regular basis are significantly better than those where an occasional operation is performed, and the chances of survival from a disease such as acute leukemia of childhood seem to be dramatically better in centers with sophisticated capabilities, including research programs. But one of the most difficult areas of all, I would assert, is our incomplete utilization of what can be called the clinical trial.

My main interests and main belief is that major advancement in medicine will result from basic research, as you may have gathered in my previous remarks. However, I have become increasingly concerned in recent years about the imperfect state of our understanding of clinical trials, which I believe will be increasingly important in the future.

In a small book called "Effectiveness and Efficiency,"

A. L. Cochran of Great Britain asserts that although the introduction of the national health system in the United Kingdom in July 1948 was highly successful in making health services available to the population at a cost that could be afforded, a very serious question is whether the increased input into the system has resulted in a comparable increase in the output--that is, improved health of the people. He claims that there are errors on both sides--that available remedies are not being used when needed and, on the other hand, that useless diagnostic and therapeutic techniques are being used. His main conclusion is that only through use of randomized clinical trials will it be possible to make a substantial improvement in health, now that an adequate system of care exists. I cannot overemphasize my own belief ⁱⁿ of the importance of an understanding, both by the medical profession and the population at large, of the need for an increased use of clinical trials as a significant and underutilized method of science to improve the health of people.

I believe ~~that~~ this country is ahead of all other countries in this respect. And yet let me give you some examples of the problems we face even here. The Director of the ~~NIA~~ ^{at NIH, Dr. Thomas C.} Clinical Center, ~~Dr.~~ Chalmers, reports that when his first studies on the use of prolonged bed rest in the treatment of hepatitis were published, ^{at} definitively demonstrating the fact that prolonged bed rest did not help, ^{at} this was greeted by some physicians as evidence that the clinical trial was not a useful device because they themselves knew from personal experience that the

reverse was true. Years later, and several studies later, most review articles--some ten out of twelve, I believe--still maintain that prolonged bed rest is useful in the treatment of hepatitis.

My own recent experience in reviewing a \$10 million, ten-year clinical trial with oral antidiabetics--which demonstrated an increased risk of cardiovascular incidents in those taking such drugs rather than insulin or diet--has been that one reason for the serious controversy over this question is simply that some ~~have not liked~~ ^{do not like} the way the results have come out.

One can bring to mind an endless group of examples: radical mastectomy for carcinoma of the breast, the use of anti-coagulants for the prevention of stroke, control of diet to prevent myocardial infarction.

As you may know, the FDA some years ago requested the National Academy of Sciences to classify a long list of drugs as to whether they were probably effective or ineffective. The lack of well-conducted clinical trials in many areas has complicated this difficult task.

Usually, though not always, it is a question of whether scientific methods can give useful information. It is often that the cost is high; that ethical considerations may limit the type of experiment that can be carried out; and that the results are sometimes not clearcut and sometimes not in keeping with the hopes of individuals. Despite these difficulties it seems to me inevitable that to improve the health of people we must become increasingly dependent on the results of fixed-protocol, multi-institutional, randomized clinical trials.

Today we face increased concern that patients not suffer undue risks in experiments involving humans. I will not dwell here on the substance of an article I prepared last fall entitled "Medical Science and Clinical Trial in Society" because it has been published in part in the New England Journal. In it I focused on clinical research and said little about the fuzzy boundary between research--usually, when under Federal guidelines, carried out to protect participants--and the practice of medicine.

Dr. ~~Thomas C.~~ ^{NIH} Chalmers, Director of the Clinical Center, ~~at NIH~~ suggests this taxonomy: First he describes the pure practice of medicine; and in this group are those diagnostic and therapeutic measures that have been established as efficacious and safe, not only through successful use over a period of time but also by well-designed clinical experiments. The number of therapeutic maneuvers in this category, he says, is distressingly small. Next, he talks about impure medical practice. And in this group lie all those procedures which are applied to patients by physicians because they may be helpful, but which lack any scientific evidence establishing their favorable risk/benefit ratio. A great deal of what physicians do for patients lies in this category, but every year one or more previously accepted therapies are found through competent clinical trials to have no real basis in fact or to be actually harmful. In the case of some procedures in this category, the evidence may demonstrate the treatment to be more harmful than helpful, but for various reasons physicians have not always accepted that evidence.

The third category has to do with clinical research that is therapeutic or diagnostic in intent, and in this case a procedure designed for the benefit of a sick patient has not been accepted by the general medical community as standard practice. A secondary aim is to obtain information of benefit to other patients with similar conditions. This is the dividing line between professional freedom in caring for the patient and the peer-review, informed-consent world of clinical research. In the case of a sick patient requiring diagnosis and treatment, it is often a matter of professional judgment as to how much the practicing physician turns to the formal structures available for the protection of the individual taking part in the research project.

Fourth, there is research in sick patients that is not intended primarily to benefit the participating patient. This is a critical category from which many of the really effective measures for controlling disease arise. The procedures are not part of the ordinary practice of medicine--even that practice designated traditionally as innovative. Informed consent, review by peers and other members of the community, and appropriate Federal guidelines are certainly applicable to this category.

Then, finally, research in normal volunteers. These are the individuals who have the most to lose and the least to gain from harmful clinical research. Informed consent and review procedures must be the most stringent for this group.

Chalmers points out that a most important aspect of the above taxonomy is that individual cases can be shifted up and down among the first four categories according to the subtleties of classification. I pointed out earlier that I think neither the medical profession nor the general public understands or accepts the clinical trial. And yet at the same time I recognize that we are now entering a period in which the protection of the research patient against undue risk may in fact lead to still more difficulties in carrying out such trials. There is the danger that overly restrictive constraints on the conduct of research involving humans will discourage such research, or alternatively that investigations will be conducted under the guise of treatment.

In conclusion, let me summarize some of the points that I feel are important in discussing the relationship of science to medicine. First, I believe that further application of science to medicine will result in increasing benefits. Indeed, the main determinant in our ability to prevent disease and cure illness in the future will be the state of knowledge, rather than any specific organizational or delivery scheme that we may have (although the latter is also important).

Secondly, I believe that there is general appreciation within the profession of the need to test new knowledge flowing from basic science laboratories when a reasonable and logical new approach to a problem is emerging, but that the careful testing of risk/benefit ratios through the application of clinical trials is less well understood or accepted, and that this area will need increased attention in the future. It tends

to be a costly type of research, one that must often be carried on over a long period, and it frequently yields less than completely definitive results. Furthermore, it tends to be less intellectually stimulating than some other types of research.

A critical factor in extending the use of clinical trials is the problem of ethical considerations which they involve. As one moves from the desperately ill and the incurable illnesses, through the non-life-threatening and mild to moderately debilitating diseases, to the normal volunteer, one must weigh increasingly both the risk/benefit and the ethical factors. When part of the cost of biomedical research is possible harm to humans, then not only must the risk and ethical considerations be thoroughly explored, but the quality of the science must be above reproach. The cost of an experiment of doubtful quality performed with test tubes is of a quite different order from that of one ^{carrying} ~~which carries~~ a risk to human health or life.

The morality of clinical trials and other clinical investigations must be judged and reevaluated in the context of existing belief. Charles Pierre Alexandre Louis, in the 1840s, wished to study the efficacy of bleeding in the pneumonias. It was not considered moral to withhold bleeding; all he could do was study the value of early versus late bleeding. His guarded conclusion was that bleeding was not as efficacious as generally believed. Even this mild statement was greeted with strident attack.

Most medical students have entered the profession because of interest in clinical, patient-oriented practice rather than because

of a desire to follow a laboratory career^g or even an in-depth study of discrete disease phenomena. The clinical trial offers a special opportunity for the patient-oriented physician to participate in the advancement of medicine.

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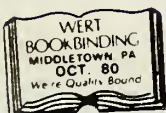
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